

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-054032
Article Type:	Original research
Date Submitted by the Author:	01-Jun-2021
Complete List of Authors:	Zadro, Joshua; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Jones, Caitlin; The University of Sydney Teng, Min Jiat; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Harris, Ian; UNSW Buchbinder, Rachele; Monash University, Dept of Epidemiology and Preventive Medicine O'Connor, Denise; Monash University, School of Public Health and Preventive Medicine McCaffery, Kirsten; The University of Sydney, Sydney Health Literacy Lab, School of Public Health Thompson, Rachel ; University of Sydney, School of Public Health Karunaratne, Sascha; Royal Prince Alfred Hospital, Surgical Outcomes Research Centre (SOuRCe) Maher, Christopher; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Hoffmann, Tammy; Bond University
Keywords:	Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Orthopaedic & trauma surgery < SURGERY

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **1 Development of a patient decision aid on subacromial decompression surgery and**
4
5 **2 rotator cuff repair surgery**
6
7

8 3 Joshua R Zadro^{a*}, Caitlin Jones^a, Ian A Harris^{a,b}, Rachelle Buchbinder^{c,d}, Denise O'Connor^{c,d},
9
10 4 Kirsten McCaffery^e, Rachel Thompson^e, Sascha Karunaratne^f, Min Jiat Teng^a, Christopher
11
12 5 Maher^a, Tammy Hoffmann^g.
13
14

15
16 6 ^aInstitute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health,
17
18 7 The University of Sydney, New South Wales, Australia.
19

20
21 8 ^bIngham Institute for Applied Medical Research, South Western Sydney Clinical School,
22
23 9 UNSW Sydney, New South Wales, Australia.
24

25
26 10 ^cDepartment of Epidemiology and Preventive Medicine, School of Public Health and
27
28 11 Preventive Medicine, Monash University, Victoria, Australia.
29

30
31 12 ^dMonash Department of Clinical Epidemiology, Cabrini Institute, Victoria, Australia.
32

33
34 13 ^eSchool of Public Health, Faculty of Medicine and Health, The University of Sydney, New
35
36 14 South Wales, Australia.
37

38
39 15 ^fSurgical Outcomes Research Centre, Royal Prince Alfred Hospital, New South Wales,
40
41 16 Australia.
42

43
44 17 ^gInstitute for Evidence-Based Healthcare, Faculty of Health Sciences and Medicine, Bond
45
46 18 University, Queensland, Australia.
47

48
49 20 *Corresponding author: Dr Joshua R Zadro - Level 10 North, King George V Building, Royal
50
51 21 Prince Alfred Hospital, PO Box M179, Missenden Road, Camperdown, NSW, 2050,
52
53 22 Australia. Telephone: +61 2 8627 6782. Email: joshua.zadro@sydney.edu.au
54
55 23
56
57 24
58
59
60

1
2
3 25 **ABSTRACT**
4

5 26 **Objective:** To develop and user test a patient decision aid that presents evidence-based
6
7 information on the benefits and harms of subacromial decompression surgery and rotator cuff
8
9 repair surgery, compared to non-surgical options.
10
11

12 29 **Design:** Mixed-methods study outlining the development of a patient decision aid (guided by
13
14 the International Patient Decision Aids Standards).
15
16

17 31 **Setting:** We assembled a multidisciplinary steering group, and used existing decision aids and
18
19 decision science to draft the decision aid.
20
21

22 33 **Participants:** People with shoulder pain and health professionals who manage people with
23
24 shoulder pain.
25

26 35 **Primary and secondary outcomes:** We interviewed participants to gather feedback on the
27
28 decision aid, assessed useability (using qualitative and quantitative methods), and performed
29
30 iterative cycles of re-drafting the decision aid and re-interviewing participants as necessary.
31
32 Interview data were analysed using thematic analysis. Quantitative data were summarised
33
34 descriptively.
35
36

37 40 **Results:** We interviewed 26 health professionals (11 physiotherapists, 7 orthopaedic surgeons,
38
39 4 general practitioners, 3 chiropractors and 1 osteopath) and 14 people with shoulder pain.
40
41 Most health professionals and people with shoulder pain rated all aspects of decision aid
42
43 usability as adequate-to-excellent (e.g., length, amount of information, presentation,
44
45 comprehensibility). Interviews highlighted agreement among health professionals and people
46
47 with shoulder pain on most aspects of the decision aid (e.g. treatment options, summary of
48
49 benefits, harms and practical issues, questions to ask a health professional, graphics,
50
51 formatting). However, some aspects of the decision aid elicited divergent views among health
52
53 professionals (e.g. causes and symptoms of shoulder pain, evidence on benefits and harms).
54
55
56
57

58 49 **Conclusion:** This decision aid could be an acceptable and valuable tool for helping people with
59
60

1
2
3 50 shoulder pain make informed treatment choices. A randomised controlled trial evaluating
4
5 51 whether this decision aid reduces people's intentions to undergo shoulder surgery and
6
7 52 facilitates informed treatment choices is underway.
8
9

10 53 **Key words:** shoulder surgery; subacromial decompression; rotator cuff repair; decision aid;
11
12 54 shared decision making.
13
14

15 55
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

1
2
3 56 **Strengths and limitations of this study**
4
5

- 6 57 - This is the first study to rigorously describe the development of a patient decision aid
7
8 58 that presents evidence-based information on the benefits and harms of subacromial
9
10 59 decompression surgery and rotator cuff repair surgery, compared to non-surgical
11
12 60 options
13
14
15 61 - We developed the patient decision aid with guidance from the International Patient
16
17 62 Decision Aids Standards, used a mixed methods approach to evaluate useability,
18
19 63 interviewed a broad range of health professionals and patients, and conducted one-on-
20
21 64 one interviews which allowed in-depth feedback on the decision aid
22
23
24 65 - Our decision aid includes several key features recommended to optimise risk
25
26 66 communication (e.g. presenting numeric estimates, presenting uncertainty, using
27
28 67 visuals, tailoring estimates)
29
30
31 68 - Limitations include a small sample size for our quantitative useability data, being
32
33 69 unable to recruit certain groups of health professionals (e.g. rheumatologists, sports
34
35 70 doctors), and only interviewing people who speak English
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1. Introduction

Subacromial decompression surgery and rotator cuff repair surgery (with or without decompression) are frequently performed for people with subacromial pain syndrome [2-5] – an umbrella diagnosis that accounts for 85% of cases of shoulder pain (including rotator cuff tears) – but evidence suggests these procedures provide limited clinical benefit. Subacromial decompression surgery is not superior to placebo (high-certainty evidence) or non-surgical options, such as exercise and glucocorticoid injections (low- to moderate-certainty evidence), for improving pain and function in people with subacromial pain syndrome [6]. Rotator cuff repair surgery is not superior to non-surgical options for degenerative rotator cuff tears (low- to moderate-certainty evidence) [7]. Serious harms (e.g. infection) are experienced by 6/1000 people that have arthroscopic shoulder surgery [6].

Use of subacromial decompression surgery and rotator cuff repair surgery is increasing globally [2-5] despite the above evidence, suggesting people may not be making informed treatment choices. In Australia, the annual number of subacromial decompression surgeries performed increased from 3,536 to 7,455 between 2000 and 2019, while the number of rotator cuff repair surgeries performed increased from 6,212 to 12,436 during this period [2]. Increases have also been reported in the United States [5], England [3, 8] and Finland [4].

Patient decision aids present unbiased information on the benefits and harms of different healthcare options. A decision aid on options for treating subacromial pain syndrome could help patients make informed treatment choices and result in less use of unnecessary surgery. A Cochrane review of 105 studies (n=31,043) found that people exposed to decision aids made more informed choices about their healthcare and had a more active role in decision making, with no negative effects on outcomes or satisfaction [9]. For some conditions, patients were also more likely to choose less invasive treatment options [9].

1
2
3 95 By eliciting views of key stakeholders, our aim was to develop a patient decision aid that
4
5 96 presents evidence-based information on the benefits and harms of subacromial decompression
6
7 97 surgery and rotator cuff repair surgery for subacromial pain syndrome (compared to non-
8
9 98 surgical options).

13 99 **2. Methods**

15 100 **2.1. Initial decision aid design**

18 101 We developed a patient decision aid with guidance from the International Patient Decision Aids
19
20 102 Standards (IPDAS) [10, 11]. We began by assembling a multidisciplinary steering group (study
21
22 103 authors) including topic experts (IH: orthopaedic surgery; RB: shoulder pain; KM, TH, RT and
23
24 104 DO: patient decision aids and shared decision making) and health professionals who manage
25
26 105 people with shoulder pain (JZ and SK: physiotherapists; RB: rheumatologist). The first draft
27
28 106 of the decision aid was created in PowerPoint and based on decision aids for antibiotics [12]
29
30 107 and knee arthroscopy [13] which several study authors have developed (TH, KM, RB, DO and
31
32 108 IH). Key features adapted from these decision aids included horizontal bar graphs displaying
33
34 109 the effects of surgery compared to non-surgical options and placebo, icon arrays to help patients
35
36 110 understand probabilities, a statement about the source and quality of the evidence, questions
37
38 111 for patients to ask their health professional, and practical issues (e.g. time off work, driving
39
40 112 restrictions). Decision science evidence suggests these features improve patient decision
41
42 113 making [14-18]. Data from the 2019 Cochrane reviews on subacromial decompression surgery
43
44 114 [6] and rotator cuff repair surgery [7] were used to inform numeric estimates of benefits and
45
46 115 harms used in the decision aid. The steering group provided feedback on the first draft before
47
48 116 we conducted semi-structured interviews with people with shoulder pain and health
49
50 117 professionals who manage people with shoulder pain.

57 118 **2.2. Participants**

1
2
3 119 Twenty-six health professionals involved in the management of shoulder pain were recruited
4
5 120 through social media, Royal Prince Alfred and Concord Hospitals in Sydney (Australia), and
6
7 121 the study authors' collaboration network. Health professionals had to manage/consult at least
8
9 122 five people with suspected subacromial pain syndrome per year. Fourteen people with self-
10
11 123 reported shoulder pain (hereafter referred to as 'patients') were recruited through social media
12
13 124 and referrals from health professionals who participated in the study. Patients had to be ≥ 18
14
15 125 years old and able to understand and communicate in English to participate. Enrolled
16
17 126 participants were asked if they had any contacts who met our inclusion criteria (snowballing).
18
19 127 We purposively sampled participants to achieve diversity in age, gender and ethnicity. For
20
21 128 health professionals, we also purposively sampled to achieve diversity in profession, years of
22
23 129 experience and country of practice. All recruitment and data collection procedures were
24
25 130 approved by the Sydney Local Health District Human Research Ethics Committee (Reference
26
27 131 number: X20-0023).

32 33 132 **2.3. Data collection**

34
35 133 Box 1 describes the data collection process including the pre-interview questionnaires (used to
36
37 134 purposively sample participants), semi-structured interviews and useability questionnaires. In
38
39 135 accordance with IPDAS guidance [10, 11], semi-structured interviews were used to assess
40
41 136 patients' views on decisional needs and clinicians' views on patients' decisional needs, gather
42
43 137 feedback on the draft decision aid, and assess useability of the decision aid. At the end of each
44
45 138 interview, participants were given the opportunity to provide any additional feedback or
46
47 139 comments. Changes to the decision aid were made throughout the interview process.
48
49 140 Modifications were compared to older versions of the decision aid to understand whether
50
51 141 changes were useful. We reported the qualitative aspect of this study according to the 32-item
52
53 142 Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Supplementary
54
55 143 File 1) [19].
56
57
58
59
60

Box 1. Data collection process**Pre-interview questionnaires used to purposively sample participants**

For health professionals, we gathered data on demographics, profession, years of experience, clinical setting, and number of patients with subacromial pain syndrome seen per year (Supplementary File 2). For patients, we gathered data on demographics (e.g., age, gender), duration and severity of shoulder pain, and previous treatments, previous imaging, and previous sick leave for shoulder pain (Supplementary File 3).

Semi-structured interviews

Interviews were used to gather feedback on the best way to present different aspects of the decision aid, such as treatment options, numeric estimates of benefits and harms, practical issues, and questions to ask a health professional. Participants were then asked to ‘think out loud’ while they read through the decision aid. They were encouraged to say everything that came to mind (e.g. concepts that might be challenging to understand, what their eye was drawn to) and give feedback on how the decision aid could be improved. The researcher conducting the interview used additional questions to prompt participants who were unsure of what to say. For example, some participants were prompted to give feedback on the relevance, usefulness, formatting, and language of each section, and the use of images.

Useability questionnaires

After the first round of interviews (n=12 health professionals; n=7 patients) and several re-drafts, we began assessing useability with a brief questionnaire at the end of each interview because we felt we were getting close to the final version of the decision aid. A separate questionnaire, adapted from The Ottawa Hospital Research Institute [1], was used for health professionals (Supplementary File 4) and patients (Supplementary File 5).

1
2
3 145 All interviews were conducted via videoconference due to COVID-19. All interviews lasted
4
5 146 between 30-60 minutes and were conducted by a researcher with experience in conducting
6
7 147 qualitative interviews (CJ). The interviewer was a female PhD candidate and occupational
8
9 148 therapist. Two pilot interviews were conducted before recruitment to test the interview guides.
10
11 149 During participant interviews, the interviewer took notes to highlight key concepts emerging
12
13 150 from the interview and direct further questioning. All interviews were audio-recorded (with
14
15 151 verbal consent obtained from participants) and transcribed verbatim for analysis. All
16
17 152 participants had the opportunity to review the transcript of their interview prior to data analysis
18
19 153 if they wished. Health professionals and patients and who completed an interview were
20
21 154 compensated for their time with a \$100 and \$50 supermarket gift card, respectively.
22
23
24
25

26 155 **2.4. Data analysis**

27
28
29 156 Pre-interview and useability questionnaire responses were summarised using descriptive
30
31 157 statistics (means and standard deviations [SD], counts and percentages). For the health
32
33 158 professional useability questionnaire (Supplementary File 4), a 5-point Likert scale (strongly
34
35 159 agree = 5; strongly disagree = 1) was used to assess agreement with various statements. We
36
37 160 presented Likert scores as the percentage of responses for each category and as means (SD).
38
39 161 We also calculated mean (SD) agreement scores for orthopaedic surgeons separately as we
40
41 162 anticipated they might have different views on a decision aid for people considering surgery
42
43 163 compared to other health professionals. For the patient useability questionnaire
44
45 164 (Supplementary File 5), impressions of different sections of the decision aid were dichotomised
46
47 165 as 'excellent/good' vs. 'fair/poor'.
48
49
50
51

52
53 166 All interview data were analysed using thematic analysis; a method for identifying, analysing
54
55 167 and reporting patterns within data [20]. Two researchers (CJ and JZ) independently familiarised
56
57 168 themselves with the interviews (via audio-recordings or transcripts), recorded initial
58
59 169 observations, and identified concepts relevant to the questions asked. The two researchers
60

1
2
3 170 developed a framework to organise concepts into broader themes and sub-themes in Excel [21].
4
5 171 Any disagreements in categorising concepts into themes and sub-themes were discussed and
6
7 172 resolved. The mapping of themes and sub-themes was iterative as new data emerged so that
8
9 173 the decision aid was continually updated before new interviews were conducted. Interviews
10
11 174 stopped once no new feedback was being provided (data saturation) and participants had an
12
13 175 overall positive impression of the decision aid.
14
15

17 176 **2.5. Patient or Public Involvement**

18
19
20 177 Patients and members of the public were not involved in the design of this study.
21

22 178 **3. Results**

23 179 **3.1. Adherence to the IPDAS criteria**

24
25
26
27 180 We determined that the decision aid (Supplementary File 6) met 6 out of 6 criteria to be
28
29 181 considered a decision aid, 6 out of 6 criteria to reduce the risk of harmful bias, and 20 and 23
30
31 182 quality criteria according to the IPDASi checklist (v4.0) [22] (Supplementary File 7).
32
33

34 183 **3.2. Participant characteristics and decision aid useability**

35
36
37 184 We interviewed 26 health professionals [11 (42%) physiotherapists, 7 (27%) orthopaedic
38
39 185 surgeons, 4 (15%) general practitioners, 3 (12%) chiropractors and 1 (4%) osteopath] and 14
40
41 186 patients. No participant who completed the pre-interview questionnaire refused an interview.
42
43 187 Health professional and patient characteristics are in Table 1. There were 15 health
44
45 188 professionals and 11 patients that completed the useability questionnaire. All aspects of
46
47 189 decision aid useability were rated as adequate-to-excellent (e.g. length, amount of information,
48
49 190 presentation, comprehensibility) by most health professionals (Table 2) and patients (Table 3).
50
51 191 Figure 1 provides a summary of the development process.
52
53
54

55 192 **3.3. Feedback on each section of the decision aid**

1
2
3 193 Positive feedback for each section, and for the decision aid overall, largely included agreement
4
5 194 with the content, graphics, formatting, amount of information, and presentation of information.
6
7
8 195 Supplementary File 8 provides a summary of themes and sub-themes across sections of the
9
10 196 decision aid. Suggestions for improvement (themes) and examples (sub-themes) are
11
12 197 summarised below. Although most suggestions were implemented, some conflicted with others
13
14 198 or were not possible to implement. Supplementary File 9 outlines feedback we did not
15
16 199 incorporate in the decision aid and our justification for this. Feedback from three or more types
17
18 200 of health professionals was classified as ‘multidisciplinary feedback’.

201 **3.3.1. Who should read this decision aid?**

202 This section covers the title of the decision aid, information about who should read the decision
23
24 203 aid, and common causes and symptoms of shoulder pain. Suggestions for improvement
25
26 204 (themes) with examples (sub-themes) included:

- 205 • Improve clarity on the target population (e.g. some GPs wanted this section to be more
26
27 206 concise, some patients thought softening the exclusion criteria would prevent people
28
29 207 with overlapping symptoms disregarding the decision aid)
- 208 • Highlight that patients need to discuss this decision aid with a health professional
30
31 209 (multidisciplinary feedback)
- 210 • Revise the causes and symptoms of shoulder pain (e.g. multidisciplinary feedback
32
33 211 suggested this information had a pathoanatomical focus that was inaccurate and that
34
35 212 this information could drive patients towards surgery)
- 213 • Use positive messaging (e.g. some physiotherapists thought the language would cause
36
37 214 fear among patients)
- 215 • Make this section more concise and relevant (e.g. multidisciplinary feedback suggested
38
39 216 the explanation of shoulder symptoms might be irrelevant for patients, some

1
2
3 217 orthopaedic surgeons wanted to emphasise the importance of a proper diagnosis to
4
5 218 guide treatment decisions)

6
7
8 219 Supplementary File 10 highlights changes between the first and final draft of this section.
9

10
11 220

12 13 14 221 **3.3.2. What are the treatment options covered in this decision aid?**

15
16 222 This section outlines non-surgical and surgical management options for subacromial pain
17
18 223 syndrome. Suggestions for improvement included:

- 19
20 224 • Include more detail on non-surgical options and how to progress management (e.g.
21
22 225 multidisciplinary feedback suggested balancing the amount of information between the
23
24 226 non-surgical and surgical options, some patients wanted more information on ‘wait and
25
26 227 see’ and how to modify activities)
- 27
28 228 • Change the non-surgical options presented (e.g. some physiotherapists thought it was
29
30 229 inappropriate to include medication and injections as options, some physiotherapists
31
32 230 and chiropractors thought the order of non-surgical options might be inappropriate)
- 33
34 231 • Include indications for surgery (e.g. multidisciplinary feedback suggested the inclusion
35
36 232 of indicators for each surgery like failed conservative management, severe pain, age
37
38 233 and massive cuff tears)
- 39
40 234 • Present evidence of benefits and harms in this section (e.g. multidisciplinary feedback
41
42 235 suggested mentioning the success rate of surgery and non-surgical options, and
43
44 236 emphasise the harms of surgery)
- 45
46 237 • Change the information on surgery (e.g. some patients wanted more detail on surgery
47
48 238 and rehabilitation, while others wanted less detail on the procedures)
- 49
50 239 • Modify the formatting and graphics (e.g. multidisciplinary feedback suggested listing
51
52 240 non-surgical options first, some patients wanted more space between the options and
53
54 241 thought the image of surgery was too graphic).

1
2
3 242 Supplementary File 11 highlights changes between the first and final draft of this section.
4
5

6 243 **3.3.3. What are the likely benefits of surgery compared to non-surgical options?**
7

8 244 This section summarises data on the effectiveness of subacromial decompression surgery and
9
10 245 rotator cuff repair surgery compared to non-surgical options from two Cochrane reviews [6, 7].
11
12

13 246 Suggestions for improvement included:
14

- 15 247
- 16 • Revise the description for the certainty of evidence (e.g. some physiotherapists and
17 chiropractors thought using a green font for high-certainty evidence would drive
18 248 patients towards surgery)
19
20 249
 - 21 • Evidence doesn't match experience, more clarification needed (e.g. some orthopaedic
22 250 surgeons thought the evidence from Cochrane reviews may not be generalizable,
23 251 surgery may improve the speed of recovery and surgery may be useful for preventing
24 252 tears progressing even if there was no improvement in symptoms, some orthopaedic
25 253 surgeons and GPs thought it was important to acknowledge evidence represents
26 254 averages and careful selection of surgical candidates could yield positive results)
27 255
 - 28 • Simplify the statistics (e.g. some physiotherapists and chiropractors thought 'key
29 256 messages' could be used instead of a bar graph, some orthopaedic surgeons thought
30 257 repetition of statistics was unnecessary and biased against surgery)
31 258
 - 32 • Provide more detail or revise the description of the evidence (e.g. some patients wanted
33 259 information on the source of the evidence and more explanation about the certainty of
34 260 evidence)
35 261
 - 36 • Contextualise the evidence to reflect uncertainty on an individual level (e.g. some
37 262 patients wanted to highlight the numeric estimates were averages)
38 263
 - 39 • Modify the formatting and language used (e.g. some GPs and patients wanted to
40 264 shorten the key messages box and include other information as footnotes, some patients
41 265 thought the icon array wasn't useful).
42 266
- 43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

267 Supplementary File 12 highlights changes between the first and final draft of this section.

268 **3.3.4. What are the likely harms of surgery?**

269 This section summarises data on the potential harms of subacromial decompression and rotator
270 cuff repair surgery from two Cochrane reviews [6, 7]. Data on the potential harms of non-
271 surgical options was not available. Suggestions for improvement included:

- 272 • Present both minor and serious harms (multidisciplinary feedback)
- 273 • Provide more context for harms (e.g. some physiotherapists and chiropractors
274 suggested comparing the harms of surgery and non-surgical options, some GPs and
275 patients thought presenting harms in a different section to ‘benefits’ doesn’t give an
276 understanding of harm versus benefit)
- 277 • Clarify the evidence as it does not match personal experience (e.g. some orthopaedic
278 surgeons thought harms were overestimated, some physiotherapists thought harms
279 were underestimated)
- 280 • Modify the formatting and language used (e.g. some orthopaedic surgeons and patients
281 thought ‘harm’ was too negative and suggested replacing it with ‘risk’).

282 Supplementary File 13 highlights changes between the first and final draft of this section.

283 **3.3.5. Summary of benefits, harms, and other practical issues**

284 This section provides a summary of the benefits, harms, and important practical issues of
285 surgery and non-surgical options. Suggestions for improvement included:

- 286 • Revise information on costs (e.g. some physiotherapists and GPs wanted specific cost
287 information on surgery, some orthopaedic surgeons wanted to soften the language
288 emphasising the costs of surgery, some chiropractors and patients wanted information
289 on the costs of non-surgical options)
- 290 • Revise information on activity restrictions and post-surgical management (e.g. some
291 physiotherapists and orthopaedic surgeons suggested alternative timeframes for post-

1
2
3 292 surgery activity restrictions, some GPs wanted to emphasise symptoms may improve
4
5 293 with or without surgery)
6
7
8 294 • Modify the formatting or language used (e.g. some GPs and patients wanted to separate
9
10 295 the practical issues by type of surgery, while some physiotherapists thought this would
11
12 296 result in too much information).

13
14
15 297 Supplementary File 14 highlights changes between the first and final draft of this section.

16 17 18 298 **3.3.6. Questions to consider when talking with a health professional**

19
20 299 This section outlines questions patients should consider asking their health professional before
21
22 300 deciding to have surgery. Suggestions for improvement included:

- 23
24
25 301 • Adding questions (e.g. some physiotherapists suggested “How long should I wait
26
27 302 before considering surgery?”)
28
29 303 • Removing questions (e.g. some orthopaedic surgeons suggested removing “Do I know
30
31 304 enough about my condition” and “Have I considered my individual circumstances?”)
32
33 305 • Modifying the formatting (e.g. some physiotherapists wanted the heading to be
34
35 306 inclusive of any health professional while others thought these questions were better
36
37 307 suited to GPs).

38
39
40
41 308 An early version of the decision aid included a section on ‘Are there other things I can do?
42
43 309 Suggestions included activity modification, strength, and endurance exercises, seeking advice
44
45 310 from a health professional, and considering surgery if these options don’t help. We received
46
47 311 positive feedback from patients on this section and helpful suggestions from health
48
49 312 professionals to add information to help people try non-surgical options first. However, we
50
51 313 decided to remove this section to save space so we could provide more detail about non-surgical
52
53 314 options on the first page.

54
55
56
57 315 Supplementary File 15 highlights changes between the first and final draft of this section.

58 59 60 316 **3.3.7. Overall feedback**

1
2
3 317 Overall feedback included:
4

- 5 318 • Reduce the amount of information (e.g. multidisciplinary feedback suggested a 2-page
6
7
8 319 decision aid was ideal, some physiotherapists and orthopaedic surgeons suggested
9
10 320 removing the question-asking section and the references)
11
12 321 • More detail needed (e.g. some GPs wanted information on imaging and the importance
13
14 322 of not missing a serious disease, some patients thought the last page lacked a solution
15
16 323 if someone had tried everything)
17
18 324 • Formatting and distribution suggestions (e.g. multidisciplinary feedback and feedback
19
20 325 from patients suggested separate decision aids for each surgery was needed, some GPs
21
22 326 wanted separate decision aids for surgical and non-surgical options, some
23
24 327 physiotherapists and chiropractors suggested making a video summary of the decision
25
26 328 aid, some physiotherapists and orthopaedic surgeons suggested the decision aid should
27
28 329 be provided in clinics, early during treatment, when patients are considering surgery
29
30 330 and/or after a patient received a diagnosis, some patients suggested emphasising the
31
32 331 question-asking section).

33 332 Some orthopaedic surgeons felt the decision aid was not balanced and biased against surgery.
34
35 333 Most patients stated that the decision aid had swayed them away from surgery, but some were
36
37 334 swayed towards surgery for various reasons (e.g. have surgery before the risk of complications
38
39 335 increases or the pain gets worse).
40
41
42
43
44
45
46
47

48 336 **4. Discussion**

49 337 **4.1. Summary of findings**

50 338 Most health professionals and people with shoulder pain rated all aspects of decision aid
51
52 339 useability as adequate-to-excellent (e.g., length, amount of information, presentation,
53
54 340 comprehensibility). Interviews highlighted agreement with most aspects of the decision aid
55
56 341 (e.g. treatment options, summary of benefits, harms and practical issues, questions to ask a
57
58
59
60

1
2
3 342 health professional, graphics, formatting, amount of information, and presentation of
4
5 343 information) and some divergent views among health professionals on parts of the decision aid
6
7 344 (e.g. causes and symptoms of shoulder pain, evidence on benefits and harms). To understand
8
9 345 whether this tool adds value to clinical practice, a randomised controlled trial evaluating
10
11 346 whether this decision aid reduces people's intentions to undergo shoulder surgery and
12
13 347 facilitates informed treatment choices is underway.

17 348 **4.2. Strengths and limitations of this study**

19 349 We developed a decision aid according to the IPDAS criteria, used a mixed methods approach
20
21 350 to evaluate useability, interviewed a broad range of health professionals and patients, and
22
23 351 conducted one-on-one interviews which allowed in-depth feedback on the decision aid. Our
24
25 352 decision aid includes several key features recommended to optimise risk communication (e.g.
26
27 353 presenting numeric estimates, presenting uncertainty, using visuals, tailoring estimates) [18].
28
29 354 Limitations include a small sample size for our quantitative useability data, being unable to
30
31 355 recruit certain groups of health professionals (e.g. rheumatologists, sports doctors), and only
32
33 356 interviewing people who speak English.

37 357 **4.3. Meaning of the study**

38
39 358 Interviews highlighted high levels of agreement with most aspects of the decision aid among
40
41 359 health professionals and patients, although we did find some divergent views among health
42
43 360 professionals on parts of the decision aid. Highly consistent feedback included praise for
44
45 361 including practical issues for surgery and non-surgical options and a global summary of the
46
47 362 benefits and harms of each, praise for including questions to ask a health professional, and a
48
49 363 comment that a 2-page decision aid would be ideal if it included all information from the 3-
50
51 364 page version. We attempted to create a 2-page version of the decision aid but were not able to
52
53 365 do so without comprising useability or removing important information.
54
55
56
57
58
59
60

1
2
3 366 Health professionals and patients largely agreed with the presentation of non-surgical and
4
5 367 surgical options, with some patients pleased to have 'wait and see' included as this aligned
6
7
8 368 with their experience of pain that has resolved without treatment. Most health professionals
9
10 369 and patients wanted non-surgical options listed before surgery to mimic treatment
11
12 370 recommendations in real-life. However, evidence suggests people are more likely to think a
13
14 371 decision aid is balanced if options are listed side-by-side [14]. We listed the options side-by-
15
16 372 side, with non-surgical options on the left ('first'), as a compromise.

17
18
19
20 373 A few physiotherapists thought it was inappropriate to include medication and injections as
21
22 374 options and wanted physiotherapy-delivered treatments listed earlier. Cochrane reviews on
23
24 375 treatments for subacromial pain syndrome show glucocorticoid injections are superior to
25
26 376 placebo and provide similar effects to non-steroidal anti-inflammatory drugs [23] and
27
28 377 physiotherapy-delivered treatments (e.g. exercise, manual therapy, electrotherapy) [24, 25].
29
30 378 There is no evidence physiotherapy-delivered treatments are superior to placebo [24, 25]. For
31
32 379 these reasons, we did not action their suggestions.

33
34
35
36
37 380 We found quite varied feedback on the causes and symptoms of shoulder pain and presentation
38
39 381 of benefits. Most health professionals and patients thought the causes and symptoms of
40
41 382 shoulder pain were accurate and easy to understand. However, some health professionals
42
43 383 (mostly physiotherapists) thought the pathoanatomical description of shoulder pain was
44
45 384 inappropriate and used language that could cause fear and drive patients towards surgery. Some
46
47 385 health professionals and patients thought the icon array and bar graphs were helpful, which is
48
49 386 consistent with evidence suggesting these graphics help people make value-aligned decisions
50
51 387 [15]. However, we replaced some icon arrays and bar graphs with a 'key messages' box to
52
53 388 address feedback that the statistics needed to be simplified and less repetitive, and because 'fact
54
55 389 boxes' are useful risk-communicating tools [26]. We kept numeric estimates in the key
56
57
58
59
60

1
2
3 390 messages box due to evidence suggesting patients prefer numeric estimates over narrative
4
5 391 descriptions of effect sizes (e.g. 'small' effects) [27].
6
7

8 392 Some orthopaedic surgeons disagreed with evidence from Cochrane systematic reviews and
9
10 393 thought the decision aid was biased against surgery. Some believed that, if surgeons selected
11
12 394 surgical candidates carefully, surgery could improve the speed of recovery and prevent tears
13
14 395 progressing (outcomes not assessed in Cochrane reviews), while minimising the risk of harm.
15
16 396 On the other extreme were some physiotherapists, who suggested that Cochrane systematic
17
18 397 reviews have underestimated the true harms of surgery. We did not change the evidence
19
20 398 presented because it is vital numeric estimates of benefits and harms in decision aids are based
21
22 399 on the highest quality available evidence [16, 28].
23
24
25
26

27 400 Nearly 3 in 4 patients thought the decision aid was biased against surgery (Table 3), likely
28
29 401 because the evidence we presented shows subacromial decompression surgery and rotator cuff
30
31 402 repair surgery are not superior to non-surgical management [6, 7]. This suggests tools for
32
33 403 assessing perceived balance of decision aids may not be suitable when a decision aid presents
34
35 404 information that counters prevailing norms.
36
37
38

39 405 **4.4. Implications for future research**

40 406 We are currently evaluating a print/online version of the decision aid in a randomised
41
42 407 controlled trial including people with shoulder pain considering shoulder surgery. However,
43
44 408 feedback from health professionals raised the possibility of future trials evaluating different
45
46 409 formats of the decision aid (e.g. video summary, decision aid specific to one shoulder surgery)
47
48 410 in different populations (e.g. patients who have consulted with a surgeon and know what
49
50 411 surgery they are likely to receive).
51
52
53
54
55

56 412 **5. Conclusion**

1
2
3 413 By eliciting views of key stakeholders, we developed a patient decision aid that presents
4
5 414 evidence-based information on the benefits and harms of subacromial decompression surgery,
6
7 415 rotator cuff repair surgery and non-operative treatments for subacromial pain syndrome.
8
9
10 416 Useability testing and interviews with health professionals and people with shoulder pain
11
12 417 highlights this decision aid could be an acceptable and valuable tool for helping people with
13
14 418 shoulder pain make informed treatment choices. A randomised controlled trial evaluating
15
16 419 whether this decision aid reduces people's intentions to undergo shoulder surgery and
17
18 420 facilitates informed treatment choices is underway.
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

421

1
2
3 **422 Authors' contributions**
4

5 423 All authors critically revised the manuscript for important intellectual content and approved
6
7 424 the final manuscript. Please find below a detailed description of the role of each author:
8
9

- 10 425 - Joshua R Zadro: conception and design, analysis and interpretation of data, drafting and
11
12 426 revision of the manuscript, and final approval of the version to be published
13
14 427 - Caitlin Jones: conception and design, analysis and interpretation of data, drafting and
15
16 428 revision of the manuscript, and final approval of the version to be published
17
18 429 - Ian A Harris: conception and design, interpretation of data, drafting and revision of the
19
20 430 manuscript and final approval of the version to be published
21
22 431 - Rachelle Buchbinder: conception and design, interpretation of data, drafting and
23
24 432 revision of the manuscript and final approval of the version to be published
25
26 433 - Denise O'Connor: conception and design, interpretation of data, drafting and revision
27
28 434 of the manuscript and final approval of the version to be published
29
30 435 - Kirsten McCaffery: conception and design, interpretation of data, drafting and revision
31
32 436 of the manuscript and final approval of the version to be published
33
34 437 - Rachel Thompson: conception and design, interpretation of data, drafting and revision
35
36 438 of the manuscript and final approval of the version to be published
37
38 439 - Sascha Karunaratne: conception and design, interpretation of data, drafting and revision
39
40 440 of the manuscript and final approval of the version to be published
41
42 441 - Min Jiat Teng: conception and design, interpretation of data, drafting and revision of
43
44 442 the manuscript and final approval of the version to be published
45
46 443 - Christopher G Maher: conception and design, interpretation of data, drafting and
47
48 444 revision of the manuscript and final approval of the version to be published
49
50 445 - Tammy Hoffmann: conception and design, interpretation of data, drafting and revision
51
52 446 of the manuscript and final approval of the version to be published
53
54
55
56
57
58
59
60

1
2
3 447 The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that
4
5 448 no others meeting the criteria have been omitted.

7
8 449 **Competing interests:** All authors declare: no support from any organisation for the submitted
9
10 450 work; no financial relationships with any organisations that might have an interest in the
11
12 451 submitted work; no other relationships or activities that could appear to have influenced the
13
14 452 submitted work.

16
17 453 **Funding source:** This study was funded by the Arthritis Australia Grants-in-Aid scheme
18
19 454 (funder number N/A). The contribution of RT to this work was supported by a National Health
20
21 455 and Medical Research Council (NHMRC) Program Grant (APP1113532).

23
24 456 **Data availability statement:** All data relevant to the study are included in the article or
25
26 457 uploaded as supplementary information.

27
28
29 458
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

1. O'Connor AM, Cranney A. User Manual - Acceptability. 1996 [Updated 2002]. Available from www.ohri.ca/decisionaid.
2. Medicare Item Reports 2000/2001 to 2018/19. http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp. Accessed 1st June, 2020.
3. Judge A, Murphy RJ, Maxwell R, Arden NK, Carr AJ. Temporal trends and geographical variation in the use of subacromial decompression and rotator cuff repair of the shoulder in England. *Bone Joint J*. 2014;96-b(1):70-4.
4. Paloneva J, Lepola V, Äärilä V, Joukainen A, Ylinen J, Mattila VM. Increasing incidence of rotator cuff repairs—A nationwide registry study in Finland. *BMC Musculoskelet Disord*. 2015;16(1):189.
5. Zhang AL, Montgomery SR, Ngo SS, Hame SL, Wang JC, Gamradt SC. Analysis of rotator cuff repair trends in a large private insurance population. *Arthroscopy*. 2013;29(4):623-9.
6. Karjalainen TV, Jain NB, Page CM, Lähdeoja TA, Johnston RV, Salamh P, et al. Subacromial decompression surgery for rotator cuff disease. *Cochrane Database Syst Rev*. 2019(1):CD005619.
7. Karjalainen TV, Jain NB, Heikkinen J, Johnston RV, Page CM, Buchbinder R. Surgery for rotator cuff tears. *Cochrane Database Syst Rev*. 2019(12):CD013502.
8. Jones T, Carr AJ, Beard D, Linton M-J, Rooshenas L, Donovan J, et al. Longitudinal study of use and cost of subacromial decompression surgery: the need for effective evaluation of surgical procedures to prevent overtreatment and wasted resources. *BMJ Open*. 2019;9(8):e030229-e.

- 1
2
3 483 9. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for
4
5 484 people facing health treatment or screening decisions. *Cochrane Database Syst Rev*.
6
7 485 2017(4):CD001431.
8
9
10 486 10. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A
11
12 487 systematic development process for patient decision aids. *BMC Med Inform Decis Mak*.
13
14 488 2013;13 Suppl 2(Suppl 2):S2-S.
15
16
17 489 11. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a
18
19 490 quality criteria framework for patient decision aids: online international Delphi consensus
20
21 491 process. *BMJ*. 2006;333(7565):417.
22
23
24 492 12. Coxeter PD, Mar CD, Hoffmann TC. Parents' Expectations and Experiences of
25
26 493 Antibiotics for Acute Respiratory Infections in Primary Care. *Ann Fam Med*. 2017;15(2):149-
27
28 494 54.
29
30
31 495 13. O'Connor D, Hoffmann T, McCaffery K, Maher C, Harris I, Glasziou P, et al. 85
32
33 496 Evaluating a patient decision aid for people with degenerative knee disease considering
34
35 497 arthroscopic surgery: Protocol for a randomised controlled trial. *BMJ Evid Based Med*.
36
37 498 2019;24(Suppl 2):A48-A.
38
39
40 499 14. Abhyankar P, Volk RJ, Blumenthal-Barby J, Bravo P, Buchholz A, Ozanne E, et al.
41
42 500 Balancing the presentation of information and options in patient decision aids: an updated
43
44 501 review. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2(Suppl 2):S6-S.
45
46
47 502 15. Carling CLL, Kristoffersen DT, Flottorp S, Fretheim A, Oxman AD, Schünemann HJ,
48
49 503 et al. The effect of alternative graphical displays used to present the benefits of antibiotics for
50
51 504 sore throat on decisions about whether to seek treatment: a randomized trial. *PLoS Med*.
52
53 505 2009;6(8):e1000140-e.
54
55
56 506 16. Montori VM, LeBlanc A, Buchholz A, Stilwell DL, Tsapas A. Basing information on
57
58 507 comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a
59
60

- 1
2
3 508 quality dimension of the International Patient Decision Aid Standards. *BMC Med Inform Decis*
4
5 509 *Mak.* 2013;13 Suppl 2(Suppl 2):S5-S.
6
7
8 510 17. Santesso N, Rader T, Nilsen ES, Glenton C, Rosenbaum S, Ciapponi A, et al. A
9
10 511 summary to communicate evidence from systematic reviews to the public improved
11
12 512 understanding and accessibility of information: a randomized controlled trial. *J Clin Epidemiol.*
13
14 513 2015;68(2):182-90.
15
16
17 514 18. Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PK, et al.
18
19 515 Presenting quantitative information about decision outcomes: a risk communication primer for
20
21 516 patient decision aid developers. *BMC Med Inform Decis Mak.* 2013;13 Suppl 2(Suppl 2):S7.
22
23
24 517 19. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research
25
26 518 (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.*
27
28 519 2007;19(6):349-57.
29
30
31 520 20. Clarke V, Braun V, Hayfield N. Thematic analysis. *Qualitative psychology: A practical*
32
33 521 *guide to research methods.* 2015:222-48.
34
35 522 21. Microsoft Corporation. Microsoft Excel [Internet]. 2018. Available from:
36
37 523 <https://office.microsoft.com/excel>.
38
39
40 524 22. Joseph-Williams N, Newcombe R, Politi M, Durand MA, Sivell S, Stacey D, et al.
41
42 525 Toward Minimum Standards for Certifying Patient Decision Aids: A Modified Delphi
43
44 526 Consensus Process. *Med Decis Making.* 2014;34(6):699-710.
45
46
47 527 23. Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain.
48
49 528 *Cochrane Database Syst Rev.* 2003(1):CD004016.
50
51
52 529 24. Page MJ, Green S, McBain B, Surace SJ, Deitch J, Lyttle N, et al. Manual therapy and
53
54 530 exercise for rotator cuff disease. *Cochrane Database Syst Rev.* 2016(6):CD012224.
55
56 531 25. Page MJ, Green S, Mrocki MA, Surace SJ, Deitch J, McBain B, et al. Electrotherapy
57
58 532 modalities for rotator cuff disease. *Cochrane Database Syst Rev.* 2016(6):CD012225.
59
60

- 1
2
3 533 26. Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug
4
5 534 benefits and harms: two randomized trials. *Ann Intern Med.* 2009;150(8):516-27.
6
7
8 535 27. Waldron C-A, van der Weijden T, Ludt S, Gallacher J, Elwyn G. What are effective
9
10 536 strategies to communicate cardiovascular risk information to patients? A systematic review.
11
12 537 *Patient Educ Couns.* 2011;82(2):169-81.
13
14 538 28. Zadro JR, Traeger AC, Décary S, O'Keeffe M. Problem with patient decision aids. *BMJ*
15
16
17 539 *Evid Based Med.* 2020 (Epub ahead of print).
18
19
20 540
21
22 541

Table 1. Characteristics of health professionals who manage people with shoulder pain (n=26) and people with shoulder pain (n=14)

Health professionals	Mean (SD) or N (%) (unless specified otherwise)
Profession	
<i>Physiotherapist</i>	11 (42%)
<i>Orthopaedic surgeon</i>	7 (27%)
<i>General practitioner</i>	4 (15%)
<i>Chiropractor</i>	3 (12%)
<i>Osteopath</i>	1 (4%)
Age (years)	40 (11)
Female	8 (31%)
Country of practice	
<i>Australia</i>	18 (69%)
<i>United States</i>	4 (15%)
<i>Canada</i>	2 (8%)
<i>England</i>	2 (8%)
Years of experience	12 (9)
Works in private practice	19 (73%)
Number of patients with shoulder pain seen per year	164 (167) Median (IQR): 100 (40-250)
People with shoulder pain	Mean (SD) or N (%) (unless specified otherwise)
Age (years)	46 (18)
Female	6 (43%)
Highest level of education	
<i>University</i>	6 (43%)
<i>High school or TAFE/Trade</i>	8 (57%)
Country of birth	
<i>Australia</i>	10 (71%)
<i>Philippines</i>	1 (7%)
<i>United States</i>	1 (7%)
<i>United Kingdom</i>	1 (7%)
<i>Egypt</i>	1 (7%)
Employment status	
<i>Working</i>	9 (64%)
<i>Not working</i>	3 (21%)
<i>Retired/unable to work</i>	2 (14%)
Health insurance	8 (57%)
Duration of shoulder pain (months)	96 (117) Median (IQR): 18 (6-180)
Activity interference in the past week	
<i>Not at all</i>	3 (21%)
<i>A little bit</i>	3 (21%)
<i>Moderately</i>	6 (43%)

	<i>Quite a bit</i>	1 (7%)
	<i>Extremely</i>	1 (7%)
Management strategies trialled		
	<i>Exercise</i>	9 (64%)
	<i>Medication</i>	8 (57%)
	<i>Rest</i>	7 (50%)
	<i>Massage</i>	6 (43%)
	<i>Manual therapy</i>	5 (36%)
	<i>Injections</i>	2 (14%)
	<i>Surgery</i>	2 (14%)
	<i>Other</i>	3 (21%)
	Previously had a scan (X-Ray, MRI, Ultrasound)	8 (57%)
	Previously had sick leave due to shoulder pain	2 (14%)

542 IQR: interquartile range; MRI: magnetic resonance imaging; N: number of participants; SD:
 543 standard deviation.

544

545

Table 2. Useability questionnaire for health professionals who manage patients with shoulder pain (n=15; nine physiotherapists, five orthopaedic surgeons and one osteopath)

Useability statements	Strongly agree, N (%)	Somewhat agree, N (%)	Neither agree nor disagree, N (%)	Somewhat disagree, N (%)	Strongly disagree, N (%)	Mean (SD)*	Mean (SD) for orthopaedic surgeons*
It will be easy for me to use	10 (67%)	4 (27%)	0 (0%)	0 (0%)	1 (7%)	4.5 (1.1)	3.6 (1.5)
It is easy for me to understand	12 (80%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	4.8 (0.4)	4.8 (0.4)
It will be easy for me to experiment with using it before making a final decision to adopt it	12 (80%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	4.8 (0.4)	4.6 (0.5)
The results of using the decision aid will be easy to see	2 (13%)	4 (27%)	7 (47%)	2 (13%)	0 (0%)	3.4 (0.9)	2.6 (0.5)
This decision aid is better than how I usually go about helping patients decide about shoulder surgery	3 (20%)	4 (27%)	4 (27%)	4 (27%)	0 (0%)	3.4 (1.1)	2.8 (0.8)
This decision aid is compatible with the way I think subacromial shoulder pain should be managed	8 (53%)	5 (33%)	2 (13%)	0 (0%)	0 (0%)	4.4 (0.7)	4.2 (0.4)
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	4 (27%)	5 (33%)	4 (27%)	2 (13%)	0 (0%)	3.7 (1.0)	3.6 (0.5)

Using this decision aid will save me time	2 (13%)	7 (47%)	4 (27%)	1 (7%)	1 (7%)	3.5 (1.1)	3.4 (1.5)
This decision aid is a reliable method of helping patients make decisions about shoulder surgery	7 (47%)	4 (27%)	1 (7%)	3 (20%)	0 (0%)	4.0 (1.2)	3.4 (1.3)
Pieces or components of the decision aid can be used by themselves	7 (47%)	7 (47%)	0 (0%)	1 (7%)	0 (0%)	4.3 (0.8)	4.2 (1.3)
This type of decision aid is suitable for helping patients make value laden choices	9 (60%)	4 (27%)	2 (13%)	0 (0%)	0 (0%)	4.5 (0.7)	4.2 (0.8)
This decision aid complements my usual approach	8 (53%)	4 (27%)	2 (13%)	1 (7%)	0 (0%)	4.3 (1.0)	3.8 (1.1)
Using this decision aid does not involve making major changes to the way I usually do things	10 (67%)	2 (13%)	2 (13%)	1 (7%)	0 (0%)	4.4 (1.0)	4.6 (0.5)
There is a high probability that using this decision aid may cause/result in more benefit than harm	4 (27%)	8 (53%)	2 (13%)	1 (7%)	0 (0%)	4.0 (0.8)	3.6 (0.9)

546 IQR: interquartile range; N: number of participants; SD: standard deviation.

547 *Likert Scale from strongly agree (5) to strongly disagree (1).

548

Table 3. Useability questionnaire for people with shoulder pain (n=11)

Useability items	N (%)
Information presented was 'excellent or good'*	
<i>Subacromial shoulder pain: should I have surgery?</i>	9 (82%)
<i>Causes and symptoms of subacromial shoulder pain</i>	8 (73%)
<i>What are the treatment options covered in this decision aid? (Non-surgical options)</i>	10 (91%)
<i>What are the treatment options covered in this decision aid? (Surgery)</i>	9 (82%)
<i>What are the likely benefits of surgery and non-surgical options?</i>	9 (82%)
<i>What are the likely risks of surgery?</i>	8 (73%)
<i>What practical issues should I consider?</i>	10 (91%)
<i>Questions to consider when talking with your health professional</i>	10 (91%)
Length of the decision aid	
<i>Just right</i>	8 (73%)
<i>Too short</i>	1 (9%)
<i>Too long</i>	2 (18%)
Amount of information	
<i>Just right</i>	10 (91%)
<i>Too little information</i>	0 (0%)
<i>Too much information</i>	1 (9%)
Presentation	
<i>Balanced</i>	2 (18%)
<i>Slanted towards surgery</i>	1 (9%)
<i>Slanted towards non-surgical options</i>	8 (73%)
Useful when deciding about surgery	11 (100%)
Makes decision to have surgery easier	8 (73%)
Enough information provided	9 (82%)

549 N: number of participants.

550 *compared to 'fair/poor'

551

552

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

553 **Figure legends**

554 Figure 1. Flowchart of the development process

555

For peer review only

1
2
3 556 **Supplementary files**
4

5 557 Supplementary File 1. Consolidated Criteria for Reporting Qualitative Research (COREQ)
6
7
8 558 checklist.

9
10 559 Supplementary File 2. Health professional questionnaire.

11
12 560 Supplementary File 3. Patient questionnaire.

13
14 561 Supplementary File 4. Useability questionnaire for health professionals.

15
16 562 Supplementary File 5. Useability questionnaire for patients.

17
18 563 Supplementary File 6. Patient decision aid.

19
20 564 Supplementary File 7. International Patient Decision Aid Standards (IPDAS) checklist.

21
22 565 Supplementary File 8. Themes, sub-themes and example quotes for each section of the decision
23
24 566 aid.

25
26 567 Supplementary File 9. Reasons for not implementing feedback for each section of the decision
27
28 568 aid.

29
30 569 Supplementary File 10. Changes between the first and final draft of ‘Who should read this
31
32 570 decision aid?’

33
34 571 Supplementary File 11. Changes between the first and final draft of ‘What are the treatment
35
36 572 options covered in this decision aid?’

37
38 573 Supplementary File 12. Changes between the first and final draft of ‘What are the likely
39
40 574 benefits of surgery compared to non-surgical options?’

41
42 575 Supplementary File 13. Changes between the first and final draft of ‘What are the likely harms
43
44 576 of surgery?’

45
46 577 Supplementary File 14. Changes between the first and final draft of ‘Summary of benefits,
47
48 578 harms, and other practical issues.’

49
50 579 Supplementary File 15. Changes between the first and final draft of ‘Questions to consider
51
52 580 when talking with a health professional.’
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

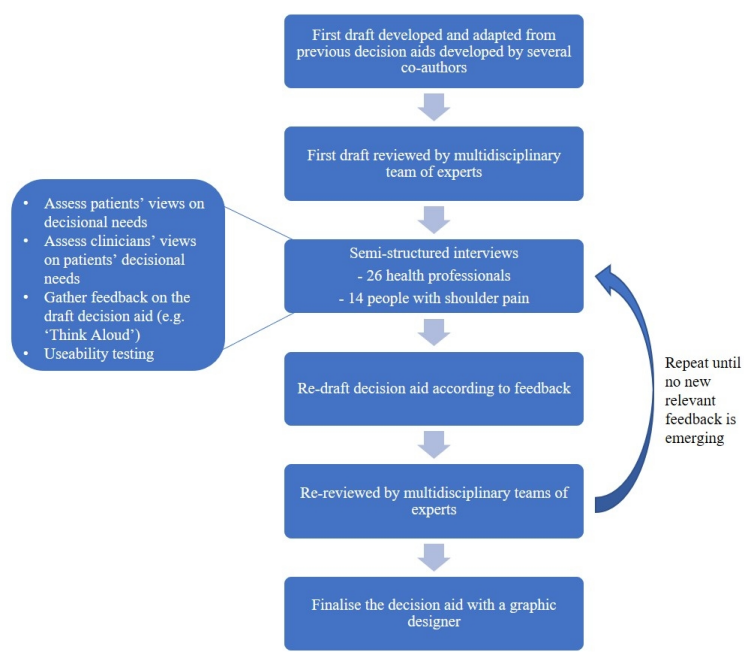


Figure 1. Flowchart of the development process

225x143mm (150 x 150 DPI)

Supplementary File 2. Health professional questionnaire

Thank you for your participation in this study, which is investigating what information health professionals feel patients need to know when considering shoulder surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-10 minutes.

First some quick questions about you...

1. Please indicate your gender:

- Female
- Male
- Prefer not to say

2. Please indicate your age: [free text response]

3. In which country do you currently practice? [free text response]

4. What health profession are you?

- Orthopaedic surgeon
- General practitioner
- Rheumatologist
- Sports medicine doctor
- Physiotherapist
- Other (please specify) _____

5. How many years have you been practicing? [free text response]

6. Which clinical setting have you spent the most time practicing in?

- Private practice
- Public hospital
- Private hospital
- Sports teams
- Other (please specify) _____

7. On average, how many patients with subacromial pain syndrome do you manage/review per year? [free text response]

Thank you for completing the questionnaire.

Supplementary File 3. Patient questionnaire

Thank you for your participation in this study, which is investigating what information patients feel is important to know when considering shoulder surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-10 minutes.

First some quick questions about you...

1. Please indicate your gender:

- Female
- Male
- Prefer not to say

2. Please indicate your age: [free text response]

3. In which country were you born? [free text response]

4. What option best describes your highest level of education?

- Primary school or less
- High school (not completed)
- High school (completed)
- TAFE/Trade
- University- undergraduate degree/s (completed)
- University- postgraduate degree/s e.g. Masters, PhD (completed)
- Other (please specify) _____

5. What is your employment status?

- Employed part-time
- Employed full-time
- Casual work
- Retired
- Unemployed
- Student
- Sick/disability leave
- Other (please specify) _____

6. Do you have private health insurance?

- Yes
- No

7. How long have you had your shoulder pain (in weeks, months or years)?

8. During the past week, how much did shoulder pain interfere with your normal work (including both work outside the home and housework)?

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- Not at all
 A little bit
 Moderately
 Quite a bit
 Extremely
9. What treatment options have you tried for you shoulder pain?
- Rest
 Medication
 Exercise
 Massage
 Manual therapy (usually provided by a physiotherapist)
 Injections
 Surgery
 Other (please specify) _____
10. Have you previously had a scan on your affected shoulder (e.g Xray, ultrasound, MRI)?
- Yes
 No
11. Have you previously taken sick leave due to shoulder pain?
- Yes
 No
12. If you have had shoulder surgery, please specify the procedure (i.e. rotator cuff repair, shaving back a bone spur, removal of bursa) [free text response]
- _____

Thank you for completing the questionnaire.

Supplementary File 4. Useability questionnaire for health professionals

The following set of questions asks about your perceptions of the decision aid you just read. We are interested in your reactions to the decision aid. Please indicate how strongly you agree or disagree with each statement by *circling* the appropriate number.

In general:	Strongly agree		→		Strongly disagree
It will be easy for me to use	1	2	3	4	5
It is easy for me to understand	1	2	3	4	5
It will be easy for me to experiment with using it before making a final decision to adopt it	1	2	3	4	5
The results of using the decision aid will be easy to see	1	2	3	4	5
This decision aid is better than how I usually go about helping patients decide about shoulder surgery	1	2	3	4	5
This decision aid is compatible with the way I think subacromial shoulder pain should be managed	1	2	3	4	5
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	1	2	3	4	5
Using this decision aid will save me time	1	2	3	4	5
This decision aid is a reliable method of helping patients make decisions about shoulder surgery	1	2	3	4	5
Pieces or components of the decision aid can be used by themselves	1	2	3	4	5
This type of decision aid is suitable for helping patients make value laden choices	1	2	3	4	5
This decision aid complements my usual approach	1	2	3	4	5
Using this decision aid does not involve making major changes to the way I usually do things	1	2	3	4	5
There is a high probability that using this decision aid may cause/result in more benefit than harm	1	2	3	4	5

Supplementary File 5. Useability questionnaire for patients

We would like to know what you think about the patient decision aid you have just read.

- Please rate each section by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Subacromial shoulder pain: should I have surgery?	Poor	Fair	Good	Excellent
Causes and symptoms of subacromial shoulder pain	Poor	Fair	Good	Excellent
What are the treatment options covered in this decision aid? (Non-surgical options)	Poor	Fair	Good	Excellent
What are the treatment options covered in this decision aid? (Surgery)	Poor	Fair	Good	Excellent
What are the likely benefits of surgery and non-surgical options? (Key message)	Poor	Fair	Good	Excellent
What are the likely benefits of surgery and non-surgical options? (What % of people report treatment success?)	Poor	Fair	Good	Excellent
What are the likely risks of surgery?	Poor	Fair	Good	Excellent
What practical issues should I consider?	Poor	Fair	Good	Excellent
Questions to consider when talking with your health professional	Poor	Fair	Good	Excellent

- The length of the decision aid was (check one):
 - Too long
 - Too short
 - Just right
- The amount of information was (check one):
 - Too much information
 - Too little information
 - Just right
- I found the presentation (check one):
 - Slanted towards non-surgical options
 - Slanted towards surgery
 - Balanced
- Would you find (or would you have found) this decision aid useful when /if you were making your decision about surgery for subacromial shoulder pain?
 - Yes
 - No
 - Comments:
- Did this decision aid/would this decision aid make your decision to have surgery:
 - Easy

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- b. More difficult
 - c. Comments:
7. Do you think we provided enough information to help people with subacromial shoulder pain decide on whether to have surgery or not?
- a. Yes
 - b. No
 - c. Comments:

For peer review only

SHOULDER PAIN: SHOULD I HAVE SURGERY?

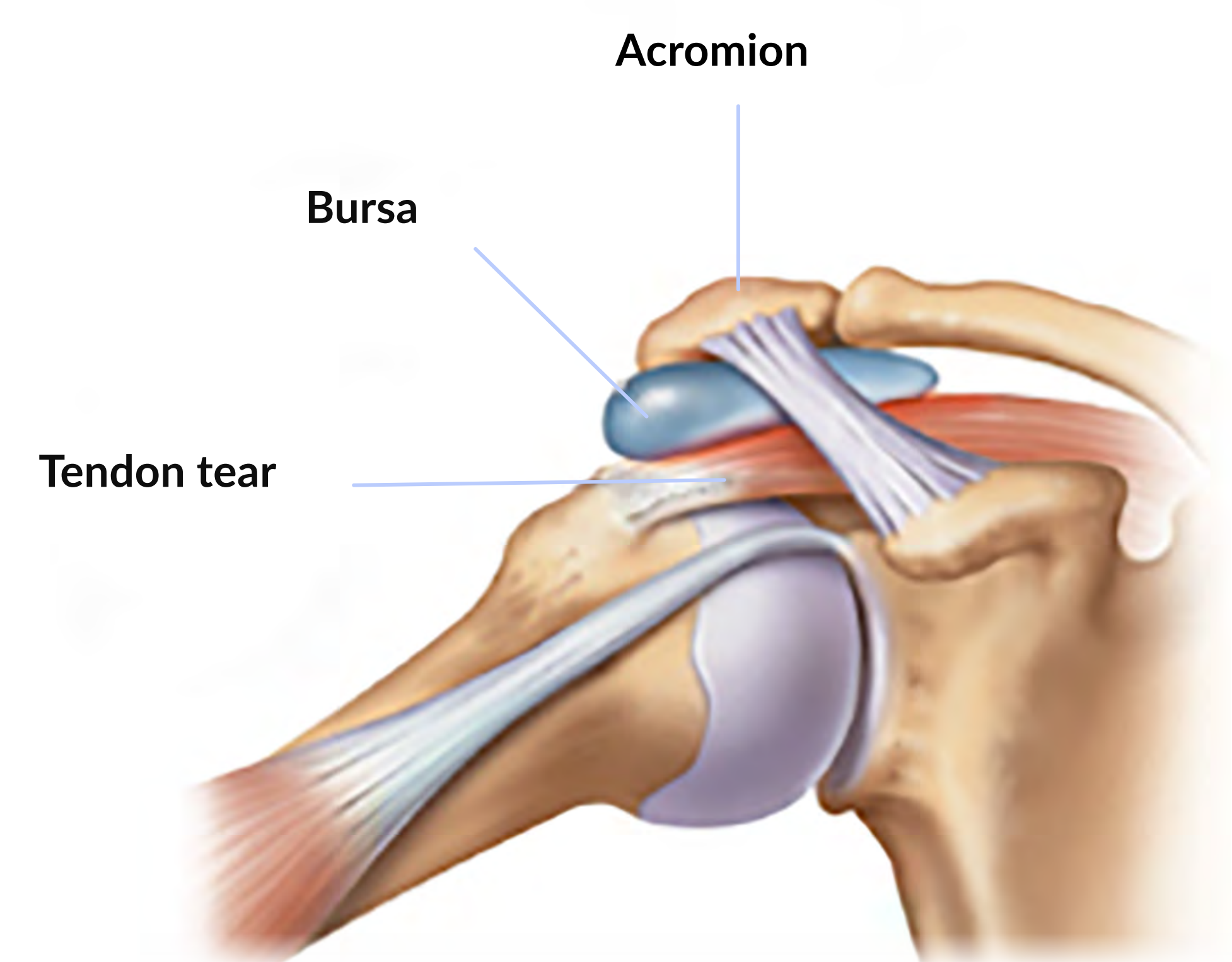
All information in this decision aid should be discussed with a health professional

+ Who should read this decision aid?

This decision aid is for people with persisting shoulder pain that is likely due to issues with rotator cuff tendons that move and support the shoulder (eg. inflammation, tears).

This type of pain often occurs around the shoulder. It makes it difficult to do simple tasks that involve lifting your arm above your head (eg. washing hair).

This decision aid does not apply to people who have other causes of shoulder pain like frozen shoulder (which causes pain and severe stiffness), osteoarthritis, or shoulder pain that begins after trauma immediately resulting in loss of movement or strength (eg. sudden rotator cuff tear, fracture, dislocation). If you're unsure of the cause of your pain, see a health professional.

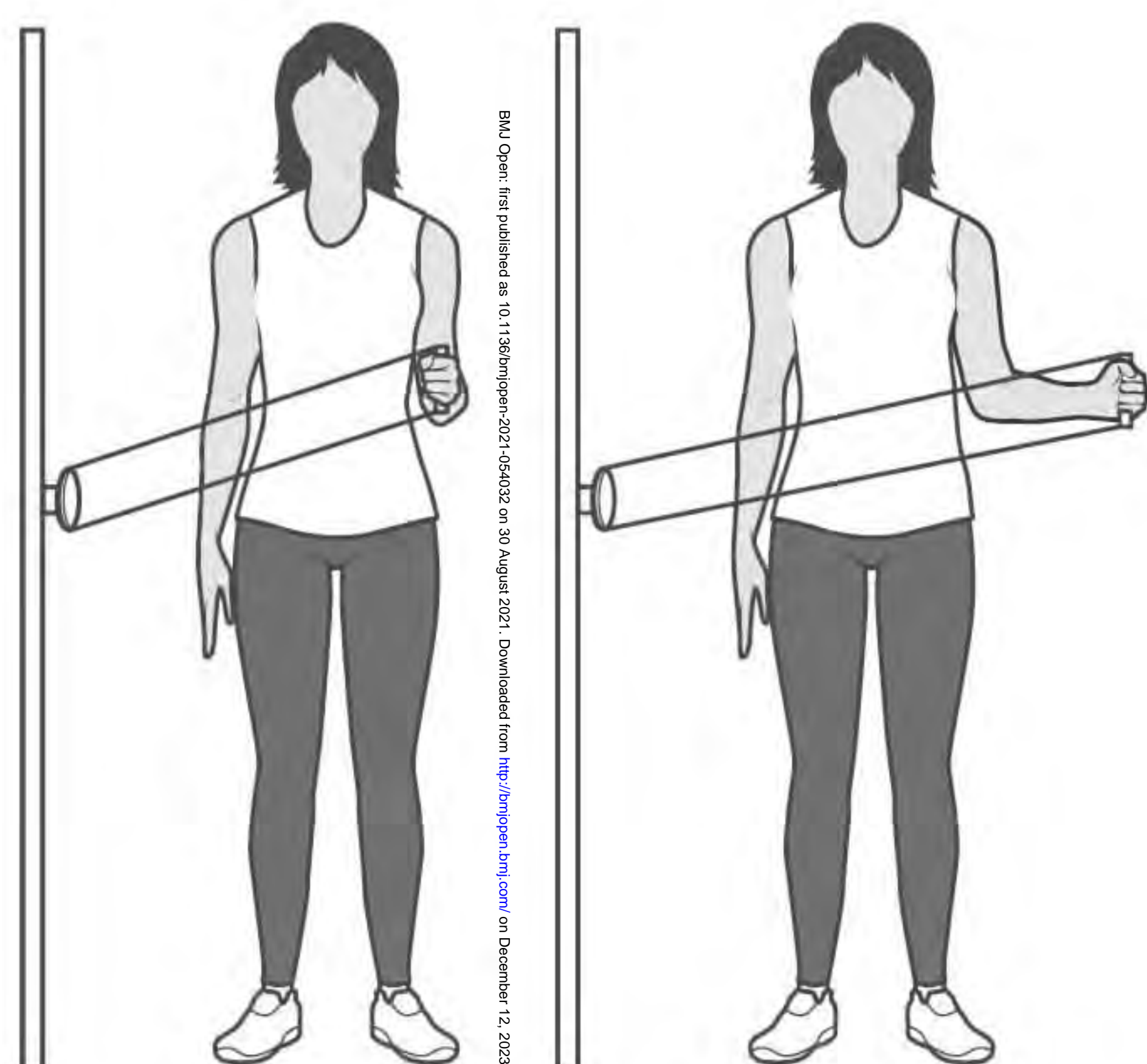


+ What are the treatment options covered in this decision aid?

NON-SURGICAL OPTIONS

Trying the following non-surgical options is recommended before considering surgery:

- Wait to see if your symptoms improve by themselves (roughly half of all people with these symptoms will recover within 6 months) and/or change your activities until the pain settles (eg. avoid carrying heavy grocery bags or take a break from sport if these activities cause pain)
- Take simple pain medicine (eg. paracetamol, anti-inflammatories)
- See a health professional (eg. physiotherapist) for advice on changing some daily activities and/or some muscle strength and endurance exercises
- See a health professional (eg. doctor) for a steroid injection



SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

You may consider surgery if the non-surgical options do not work and you can no longer put up with the pain. Typically surgery is not performed unless you have had symptoms for at least 3-6 months.

Surgery requires staying in hospital, having an anaesthetic and small skin cuts in your shoulder so the surgeon can perform one or both of the following:

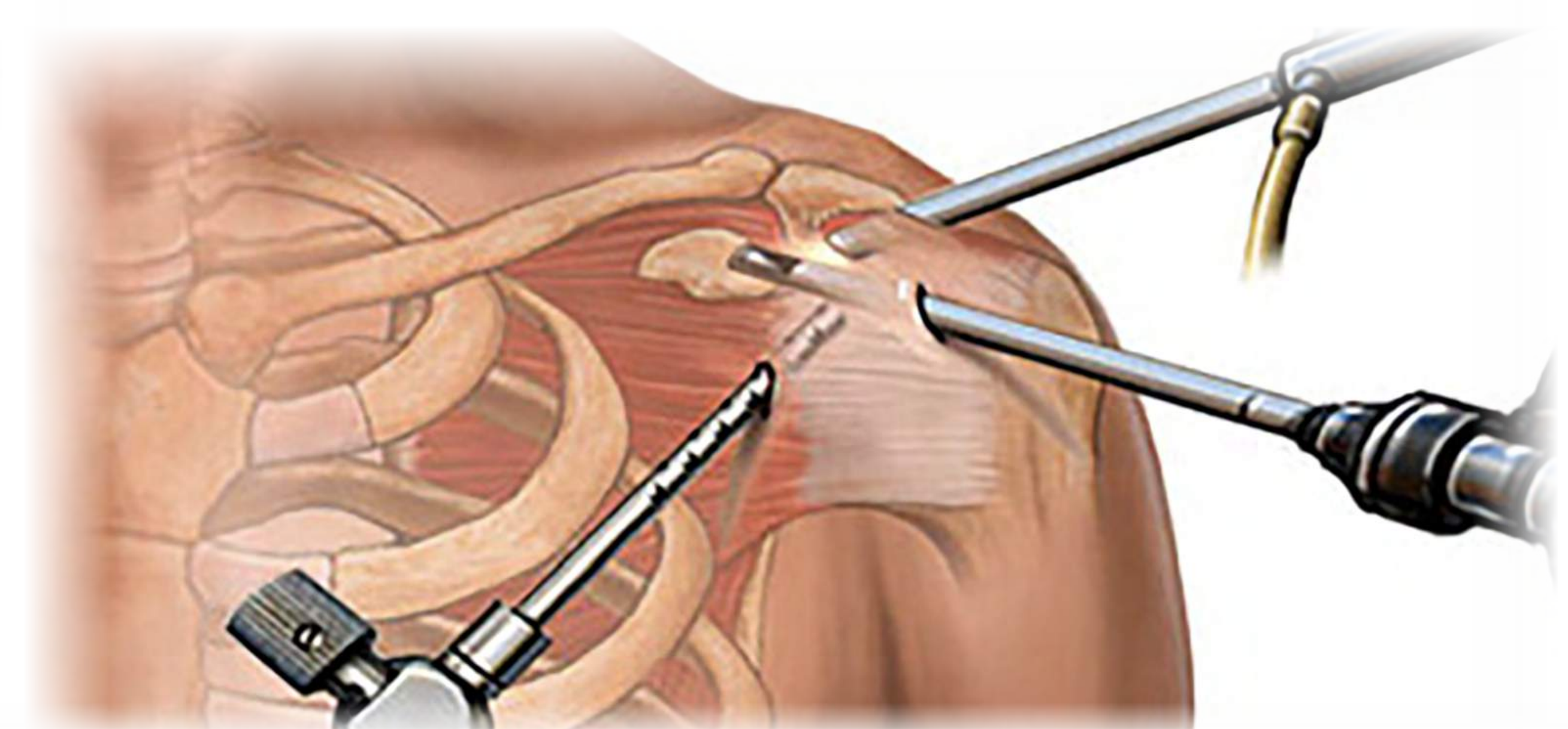
✓ Subacromial decompression surgery

Increase the space under the acromion by either shaving back some bone, trimming some ligament and/or removing a bursa

✓ Rotator cuff repair surgery

Reconnecting torn rotator cuff tendons

You will need to have rehabilitation involving exercises for at least 3 months following surgery. Much of this rehabilitation can be done at home.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

+ What are the likely benefits of surgery compared to non-surgical options?

The figures on this page are based on the most up-to-date medical research as of 2020 (see references at the bottom of this page)

KEY MESSAGE

On average, patients report that surgery **improves pain and function by less than 10%** (ie. an improvement in pain or function of less than a 1 point on a 0-10 pain scale) compared to non-surgical options in the short term (6 months after) and longer term (1-2 years after) ^c. Because most patients do not notice these improvements, research concludes:

- Subacromial decompression surgery is not better than placebo or non-surgical options (ie. injections, exercise, medication or no treatment) for people with shoulder pain and no full-thickness rotator cuff tears ^A
- Rotator cuff repair surgery is little-to-no better than non-surgical options for people with full-thickness rotator cuff tears ^B

These results are averages. Surgery improves pain and function by more than 10% for some patients. But other patients have either **no improvements or worse** pain and function after surgery.

Further information:

^A For subacromial decompression surgery, we are very confident about this key message because research on this surgery is high-quality. This research was mostly conducted on people aged in their 40s, 50s and 60s, but is the best evidence we have for all ages.

^B For rotator cuff repair surgery, we are somewhat confident about this message because there is lack of high-quality research on this surgery. This research was mostly conducted on people aged in their 50s and 60s but is the best evidence we have for all ages. Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon.

^c Research suggests exercise or activities that you can do yourself at home may be just as helpful as a supervised exercise program.

- What are the likely harms of surgery?

Think of each figure as 1 person. We can't predict if you will be one of the people who is harmed. Harms are more common among people with other health conditions (e.g. diabetes, heart disease).

- has frozen shoulder or minor harms
- has serious problems



About 3 people per 100 that have surgery will develop frozen shoulder (which may cause shoulder pain and stiffness for up to 2 years) or minor harms with surgery.



About 1 person per 100 that has surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, heart attack, stroke and pneumonia.

Important information: The information in this decision aid is not intended as medical advice and should not be used as a substitute to seeing a qualified health professional who can determine your medical needs.

References: 1) Karjalainen TV, et al. Cochrane Database Syst Rev. 2019, Issue 1. Art. No.: CD005619;
 2) Karjalainen TV, et al. Cochrane Database Syst Rev. 2019, Issue 12. Art. No.: CD013502;
 3) Page MJ, et al. Cochrane Database Syst Rev. 2016, Issue 6. Art. No.: CD012224.

+ Summary of benefits, harms, and other practical issues

NON-SURGICAL OPTIONS

✓ Potential benefits

- May **improve by itself** (within 6 months half of people will recover) or with non-surgical options (ie. injections, exercise, or medication)
- **Avoid surgery**

− Potential harms

- May decide to **have surgery later**
- **Cost of non-surgical options** (eg. injection, physiotherapy)
- **Time to attend health appointments** (eg. for physiotherapy)
- Regardless of what treatment you have, your symptoms **may not improve**

SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

✓ Potential benefits

- May provide **slight improvement in pain and function** compared to non-surgical options

− Potential harms

- Possible **surgical harms** (eg. frozen shoulder, infection)
- Your symptoms **may not improve** with surgery
- **Symptoms will temporarily be worse after surgery** due to the operation (eg. pain when sleeping or moving your arm)
- **Rehabilitation for 3-12 months** after surgery and time to attend rehabilitation
- May take up to **6 weeks** after subacromial decompression and **12 weeks** after rotator cuff repair to perform daily activities (eg. reach above your head, lift heavy objects)
- May take **3-4 months** after subacromial decompression and **6-12 months** after rotator cuff repair to return to heavy manual work, exercise, or sport
- **Out-of-pocket costs** are generally higher for surgery than non-surgical options. There may be **costs for rehabilitation** after surgery and due to **time needed off work**

+ Questions to consider when talking with a health professional...

- 🔍 Do I need surgery? What happens if I don't have surgery? What happens if I do nothing?
- 📊 Is surgery suitable for me? Which surgery is suitable for my diagnosis?
- 👤 Can I have surgery later? If so, how long should I wait before considering surgery?
- ➕ Have I considered my situation before making any decisions (eg. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport, etc)?
- 📋 Do I understand enough about my condition and the benefits and harms of having surgery and not having surgery?



Discloser: Arthritis Australia provided funding to develop this tool but had no involvement in the development process. The developers of this decision aid include orthopaedic surgeons, rheumatologists, physiotherapists, psychologists and occupational therapists, who have a range of views on the information in this decision aid. 8/11 developers have a PhD. None of the developers will gain or lose anything based on the choices that people make. Feedback from people with shoulder pain and health professionals practicing in various countries was used to refine the information presented in this decision aid.

Last reviewed: 27/05/21. Update due 27/05/21.

Lead developer: Dr Joshua Zdro, Institute for Musculoskeletal Health, University of Sydney, Australia.

Supplementary File 7. International Patient Decision Aid Standards checklist (IPDASi v4.0)

Qualifying criteria	Answer
1. The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required.	Yes
2. The patient decision aid explicitly states the decision that needs to be considered (index decision).	Yes
3. The patient decision aid describes the options available for the index decision.	Yes
4. The patient decision aid describes the positive features (benefits or advantages) of each option.	Yes
5. The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option.	Yes
6. The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	Yes
Certification criteria	Answer
1. The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	Yes
2. The patient decision aid (or associated documentation) provides citations to the evidence selected.	Yes
3. The patient decision aid (or associated documentation) provides a production or publication date.	Yes
4. The patient decision aid (or associated documentation) provides information about the update policy.	Yes
5. The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as “our best estimate is . . .”).	Yes
6. The patient decision aid (or associated documentation) provides information about the funding source used for development.	Yes
7. The patient decision aid describes what the test is designed to measure.	N/A
8. If the test detects the condition or problem, the patient decision aid describes the next steps typically taken.	N/A
9. The patient decision aid describes the next steps if the condition or problem is not detected.	N/A
10. The patient decision aid has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).	N/A
Quality criteria	Answer
1. The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate).	Yes
2. The patient decision aid makes it possible to compare the positive and negative features of the available options.	Yes
3. The patient decision aid provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions).	Yes
4. The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply.	Yes

5. The patient decision aid specifies the event rates for the outcome probabilities	Yes
6. The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	Yes
7. The patient decision aid allows the user to compare outcome probabilities across options using the same denominator (when feasible).	Yes
8. The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams).	Yes
9. The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly).	Yes
10. The patient decision aid provides a step-by step way to make a decision.	Yes
11. The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	Yes
12. The development process included a needs assessment with clients or patients.	Yes
13. The development process included a needs assessment with health professionals.	Yes
14. The development process included review by clients/patients not involved in producing the decision support intervention.	Yes
15. The development process included review by professionals not involved in producing the decision support intervention.	Yes
16. The patient decision aid was field tested with patients who were facing the decision.	Yes
17. The patient decision aid was field tested with practitioners who counsel patients who face the decision.	Yes
18. The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	Yes
19. The patient decision aid (or associated documentation) describes the quality of the research evidence used.	Yes
20. The patient decision aid includes authors'/developers' credentials or qualifications.	Yes
21. The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	No
22. There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	No*
23. There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	No*
24. The patient decision aid includes information about the chances of having a true-positive test result.	N/A
25. The patient decision aid includes information about the chances of having a true-negative test result.	N/A
26. The patient decision aid includes information about the chances of having a false-positive test result.	N/A
27. The patient decision aid includes information about the chances of having a false-negative test result.	N/A
28. The patient decision aid describes the chances the disease is detected with and without the use of the test.	N/A

1
2
3 N/A: not applicable.

4 *we are in the process of evaluating the decision aid in a randomised controlled trial.
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Supplementary File 8. Themes, sub-themes and example quotes for each section of the decision aid.

Themes	Sub-themes	Example quotes (abbreviation for type of health professional comes first, where applicable)
WHO SHOULD READ THIS DECISION AID?		
Positive feedback	Health professionals	
	Causes of shoulder pain and graphics were appropriate [PT/OS/OP]	OP, Female 40-49 yrs old – "I think the description is really quite good and that's the sort of language that I would usually use to describe what's happening as well."
	Patients	
	Clear explanation of the target population	Female 40-49 yrs old – "I like the way it breaks down the different types of shoulder pain within the broader subsection of subacromial shoulder pain."
	Helpful graphic of shoulder joint anatomy image	Male 30-39 yrs old – "I can understand it clearly, it helps having the picture there to be able to visualise it."
Improve clarity on the target population	Health professionals	
	Make the information more specific to a diagnosis [OS/PT]	OS, Male 40-49 yrs old – "We haven't even reached the stage where a diagnosis is made...shoulder pain is not a diagnosis."
	Differentiate between degeneration and traumatic rotator cuff tears [OS/OP]	OS, Male 40-49 yrs old – "Sometimes someone may develop inflammation...from an acute pinching of that bursa or the tendon. Or someone can have a traumatic event and actually tear their rotator cuff and it may resemble an impingement problem or they may be older patients and have chronic impingement pain, developing degenerative changes in the tendons in that region."
	Make the section more concise [GP]	GP, Female 30-39 yrs old – "There's a lot to look at and sometimes that can be overwhelming for some

		patients, I think they'll receive it but then maybe put it aside."
	Provide more detail on alternative diagnoses for shoulder pain [PT/OP/OS]	OS, Male 50-59 yrs old – "You certainly have covered some of the key things it can cause shoulder pain, but the other thing that's missing is that shoulder pain may come from elsewhere, for example cervicogenic pain."
	Patients	
	Make it clear the decision aid is for people with subacromial impingement syndrome (e.g. include the diagnosis in the title)	Male 30-39 yrs old – "Rotator cuff tears or impingement or bursitis should be the title, because that's really the patient demographic that you're looking at... Just 'shoulder pain' in general is a little bit vague at this point."
	Simplify 'subacromial shoulder pain' (e.g. 'shoulder pain')	Male 20-29 yrs old – "How necessary is it that you have subacromial in there? ... My first reaction was "oh wow, these are words that I don't understand, maybe this isn't for me.""
	Soften the exclusion criteria to avoid people with overlapping symptoms disregarding the decision aid	Female 40-49 yrs old – "One of the problems that I had is that frozen shoulder is not a very clear diagnosis and there could be overlap with subacromial shoulder pain. It [decision aid] might be still relevant to some people who have a potential diagnosis of frozen shoulder."
	Re-word or re-format this information	Female 40-49 yrs old – "'Do not read this form' is very clear but possibly, being in red, sounds quite alarmist."
	Health professionals	
Highlight that patients need to discuss this decision aid with a health professional	Emphasise that patients should discuss the decision aid with a health professional [OS/PT/GP]	OS, Female 50-59 yrs old – "The more information a patient has the better, I would love it if a patient came with something like this and said what do you reckon and then we could talk about their individual issue."
	Title needs to be revised [PT]	PT, Male 40-49 yrs old – "When you say at the top 'Shoulder pain should I have arthroscopic surgery?'

Why is that even a question? Why can't it be 'Shoulder pain', should I have a professional consultation?

	Health professionals	
	Information has a pathoanatomical focus that is inaccurate [PT/OS/CP]	CP, Male 20-29 yrs old – "It does make it sound very pathoanatomical which it can definitely be in a lot of cases but in that first description it almost seems like it's a couple of options that it could be, either rotator cuff tear or bursitis and there's definitely some other things to consider there."
	Information could drive patients towards surgery [CP/PT/OS]	PT, Male 20-29 yrs old – "So this first page if I were to be a patient looking at this I'd be like ok well this is clearly pointing me towards having surgery."
Revise the causes and symptoms of shoulder pain	Clarify that shoulder pain can be caused by overuse and work (e.g. heavy lifting) [GP/PT]	GP, Female 30-39 yrs old – "I find that most of the patients that I see that have it tend to be a middle aged group having used a lot of overhead repetitive activities."
	Re-format or re-word this information [PT/OS]	OS, Male 60-69 yrs old – "I know it's a lay term, the 'inflamed tendons' but 'degenerative rotator cuff tears' is often what we're dealing with."
	Patients	
	Describe what causes the structural issues associated with shoulder pain (e.g. explain why a tendon tears or a bursa gets inflamed)	Female 60-69 yrs old – "I suppose when somebody gets a sore shoulder you want to know, whether it's a swollen bursa, whether it's a tear, what's actually causing it?"
	Provide more information about potential aggravating activities (e.g. lifting overhead)	Male 20-29 yrs old – "Or even just 'your hands above your head' or something like that."
	Avoid jargon	Male 20-29 yrs old – "Non-medical folks are the people who haven't been seeing a doctor or YouTubing or Googling shoulder pain, are not going to be familiar with this."
Use positive messaging	Health professionals	

bmjopen-2021-054032, 2021, 1, Downloaded from <http://bmjopen.bmj.com/> on December 17, 2022, by guest, protected by copyright.

	Language will cause fear among patients [CP/PT]	CP, Male 20-29 yrs old – "There's a lot of very scary language in here too which is very nocebic; inflamed tendons, impingement, tears, swelling, fluid filled. Which for someone...see those things and think there's something very seriously wrong with me when there really very well might not be."
	Include positive messaging about prognosis and what pain means (e.g. pain doesn't equal damage, pain may get better with time, imaging findings are common in people without symptoms) [CP/PT/OP]	CP, Male 20-29 yrs old – "Having a line like that in there that most people with shoulder pain get better on their own with time - stay positive."
	Health professionals	
	Too much information [PT/CP/OS]	CP, Male 20-29 yrs old – "For the sake of just having a printout to give to somebody definitely the more visual and less words is probably good. I'm just thinking of it from a patient perspective where they want simplicity with direct answers."
Make this section more concise and relevant	Explanation of shoulder symptoms might be irrelevant for patients [GP/OS/PT]	PT, Female 30-39 yrs old – "I'm just wondering if the line of 'shoulder pain often makes it difficult to do simple everyday tasks' really needs to be there, these people will know that."
	Graphic of pain distribution might be more useful than a graphic of the shoulder anatomy [OS/PT]	OS, Male 40-49 yrs old – "I think a surface-based picture showing a highlighted area of pain going down the lateral part of their arm may be more useful than an anatomical picture."
	Remove the word 'arthroscopic' from decision aid [OS]	OS, Male 40-49 yrs old – "There's still debate on what's the best surgery for certain things, like open or arthroscopic."
WHAT ARE THE TREATMENT OPTIONS COVERED IN THIS DECISION AID?		
Positive feedback	Health professionals	

Graphic of surgery, details about surgery, non-surgical options are appropriate [PT/CP/OS] PT, Male 40-49 yrs old – "The thing is with arthroscopic repair you'd never do it justice with any type of picture anyway, so any general picture there would be fine. It doesn't scare me away, it looks gentle, plus I've been in the OR anyway."

Important that rehabilitation following surgery is highlighted [PT/OP/OS] OP, Female 40-49 yrs old – "To talk about rehabilitation, I think it is really responsible and important."

Patients

Order of options, description of options, formatting of information on surgery, including 'wait and see' as an option are appropriate Male 20-29 yrs old – "I do think those non-surgical options are important, that first one 'wait to see if your pain goes away'. I read that and go yeah, every single time my pain has eventually gone away."

Important to emphasise the downsides of surgery (e.g. long rehabilitation, anaesthetic) Male 20-29 yrs old – "That's definitely also pretty clear. I think the 3 to 12 months rehabilitation bracket, that would kind of freak me out a bit to see that upper band there."

Graphic of surgery was helpful to understand it is an invasive procedure Male 30-39 yrs old – "I think that does a good job of showing what they're planning on doing and that it's not something simple."

Health professionals

Balance the amount of information between non-surgical and surgical options [CP/PT/OS/GP/OP] PT, Female 30-39 yrs old – "I would look at those two options and get there's all this information about surgery and under no surgery there's just a few words, surgery must be the more involved better option for me because it looks bigger."

More detail needed on rehabilitation after surgery [PT] PT, Male 40-49 yrs old – "It may be the same commitment or greater than conservative rehab, so you just have to be aware that it's not just fixed...now you have to follow this rehabilitation protocol."

Include more detail on non-surgical options and how to progress management

bmjopen-2021-054033-1 on 23 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46	<p>Need a flowchart of non-surgical options [PT]</p> <hr/> <p>Highlight how long patients should try different non-surgical options before surgery [GP/PT]</p> <hr/> <p>More detail is needed on muscle strengthening programs [PT]</p> <hr/> <p>Include evidence for non-surgical options [PT/OS]</p> <hr/> <p>Emphasise the need for shared decision making [CP]</p> <hr/> <p>Patients</p> <hr/> <p>Provide more non-surgical options</p> <hr/> <p>Provide evidence for various non-surgical options (e.g. options listed in the decision aid, lifestyle change, TENS, ultrasound, hydrotherapy, massage, diet, acupuncture, Chinese herbs)</p> <hr/> <p>Provide more information on activity restrictions and how to modify activities while in pain</p>	<p>PT, Female 30-39 yrs old – "Yeah maybe even a flow chart of some kind...Is it a new event? Yes. Was it a full rupture? Yes, so you have surgery."</p> <hr/> <p>GP, Male 50-59 yrs old – "If they are younger, I won't let them wait for six months, if they're not better within 4 to 6 weeks I'm probably sending them off to a surgeon if they have a torn tendon."</p> <hr/> <p>PT, Male 20-29 yrs old – "Maybe a greater emphasis on what the current evidence shows...that strengthening can make a difference and even time with doing the right things could improve it."</p> <hr/> <p>OS, Female 50-59 yrs old – "I think it's important for them to know that if they wait long enough it will probably settle on its own, and we know the studies support that."</p> <hr/> <p>CP, Male 20-29 yrs old – "It's always going to be a shared decision making process, it's always going to take into account the patients values and what their lifestyle is like, how much this is impairing them."</p> <hr/> <p>Female 50-59 yrs old – "There's not a lot of options...I think it's telling me in my particular case that it's inevitable that I would have to have surgery eventually."</p> <hr/> <p>Female 60-69 yrs old – "This has taught me a lot about surgery, whether to get surgery or not, but it hasn't told me a lot about whether cortisone injections are better than not having cortisone injections or whether physio is better than having no physio. "</p> <hr/> <p>Female 60-69 yrs old – "I would like to know if I need to do anything or if it's just going to take time regardless of what you do...Or whether you should</p>
---	--	---

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

just continue doing everyday things like vacuuming and things like that even though it's a little bit painful."

Highlight whether delaying surgery or non-surgical treatment is harmful or not
Female 60-69 yrs old – "I'd read a lot about that, where they said if you wait too long its irreparable sort of thing, Dr Google again."

Provide more information on 'wait and see' (e.g. highlight that you can trial non-surgical options while you 'wait and see')
Male 30-39 yrs old – "I think 6 months is a long time to wait and deal with an issue without seeking advice."

Present information in a way that helps patients understand the importance of non-surgical options
Male 30-39 yrs old – "Is there a recommendation from the health board or something where it says 'non-surgical option is recommended?'"

Health professionals

Inappropriate to mention medication and injections as options [PT/CP]
PT, Male 40-49 yrs old – "Personally I balk at the steroid injection option because the evidence for that is so poor. There's reasonably strong emerging evidence that its adverse effects are pretty high."

Re-format or re-word information on non-surgical options [OS/PT]
PT, Female 30-39 yrs old – "Rather than saying 'see a doctor for a corticosteroid injection' I would say 'discuss the options of a corticosteroid injection with the doctor.'"

Change the non-surgical options presented

Label 'no surgery' as something more positive (e.g. conservative, exercise-based) [PT]
PT, Male 40-49 yrs old – "I wouldn't call it 'no surgery', I would call it either 'conservative', 'exercise'... 'physio exercise therapy', 'strengthening therapy'..."

Do not mention specific exercises in the decision aid [GP]
GP, Female 30-39 yrs old – "Generally [patients] won't do [exercise] if they didn't pay money [to see a physiotherapist], if they didn't invest time into it they're not going to take on board the advice as much."

Mention the benefits of ultrasound for diagnosis and guiding injections [GP]
GP, Female 60-69 yrs old – "The other thing would be usefulness of ultrasound for the diagnosis...especially if you do ultrasound guided steroid injections."

bmjopen-2021-054033 on 130 August 2021 at 11:30 AM by guest. Protected by copyright.

1		
2		
3		
4	Waiting 6 months might be too long for patients to do nothing	OP, Female 40-49 yrs old – "I think to wait six
5	[PT/OP]	months, which is really the implication of that first
6		one, would be a long time for people in pain."
7	Order of non-surgical options might be inappropriate [CP/PT]	CP, Male 20-29 yrs old – "The order of the bullet
8		points, I mean hopefully they're not in any sort of
9		order of priority, to go straight to anti-inflammatories,
10		I'm biased towards non-pharmacological first."
11		
12	Health professionals	
13	Include indications for each surgery (e.g. failed conservative	GP, Female 30-39 yrs old – "Maybe in the decision
14	management, severe pain, age, rotator cuff tear, impingement,	making tool just clearly outlining the reasons for why
15	elite sports participation, massive cuff tears) [GP/OS/CP/PT]	you'd then become a surgical candidate."
16	Highlight that imaging findings in isolation aren't indications	OS, Female 50-59 yrs old – "It's not relevant to me
17	for surgery [PT/OS]	what the imaging says, it's relevant what the patient's
18		symptoms and signs are."
19		
20	Important for patients to know which procedure they are most	OS, Male 40-49 yrs old – "That's what I say to a lot of
21	likely to receive as this could influence recovery and	my patients, obviously it's very much dependent on
22	rehabilitation needs [OS]	the diagnosis and the anatomy of what's going on."
23	Re-format or re-word indications for surgery [PT]	PT, Male 30-39 yrs old – "I guess putting option one
24		and two there kind of implies that they have to have
25	Include indications for	surgery afterwards."
26	surgery	
27	Highlight that surgery may improve symptoms or anatomy but	OS, Female 50-59 yrs old – "I say to them their rotator
28	not address the cause [PT/OS]	cuff has got a headache, the surgery can take the
29		hammer away but you will still have the headache and
30		that headache will take time to improve. Unless you do
31		the anti-inflammatories and the rehabilitation therapy
32		that headache won't go away even if you have
33		surgery."
34		
35	Patients	
36	Provide more detail on the indications for surgery (e.g.	Male 20-29 yrs old – "I wonder about in that first
37	worsening pain)	underlined sentence...if the above options don't work,
38		if you can't live with the pain, or something like the
39		
40		
41		
42		
43		
44		
45		
46		

above options are not feasible, you can't rest because you have to work."

Health professionals

Make the uncertainty of options clear [PT/OS]

OS, Female 50-59 yrs old – "By 6 months 75% are much better than they were before surgery. But would they have been there without surgery as well? Don't know. I think it's a hard question and we all think as surgeons that our surgery does wonderful things, that's one of the downsides of talking to surgeons we'll say we're fantastic and everything works really well."

Present evidence of benefits or harms in this section

Mention the success rate of surgery and non-surgical options [GP/PT/OS]

OS, Male 60-69 yrs old – "When I'm talking about the things that will help them and then get onto surgery, but also talk to them about things a lot of people spend a lot of money on, there's no evidence that they work as well."

Emphasise the harms of surgery [PT/CP/GP]

CP, Male 20-29 yrs old – "A 1% chance of you potentially dying from the surgery when it's no better than anything else that's a big risk but it doesn't sound like a lot."

Health professionals

Provide more detail on rehabilitation (e.g. time frames, will determine success, can be performed at home) [PT/OS/GP]

GP, Female 30-39 yrs old – "Surgery by itself is useless, if you're going to go through surgery expect a lot of rehab and if you can't commit to the rehab you're better off not going through surgery."

Change information on surgery

Include more details about the procedures [PT/OP/OS]

PT, Male 40-49 yrs old – "You could even explain a little more about the surgery, I think it's even ok to say a little more."

Re-format or re-word information on surgery [PT/OS]

OS, Male 40-49 yrs old – "I think again there's too much writing having lines like 'pain you can't deal with' is pushing the patient...again it's too wordy, so you would just say 'surgery is an option.'"

bmjopen-2021-054032 on 30 August 2021 by guest. Protected by copyright.

For Peer Review

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

1
2
3 Include details on recovery, comparing surgery to non-
4 surgical options [PT/CP/OS]
5
6
7

PT, Male 20-29 yrs old – "One example recently I had a shoulder patient and they got surgery and regretted it. They were saying they didn't know how much they would go backwards and how long it would take and the restrictions."

8
9 **Patients**

10 Provide less information on surgery

Male 20-29 yrs old – "The two different procedures, I haven't been to a doctor or physio about this, these are big words. Am I one? Am I the other? I don't really know. Do I care? Is it important?"

11
12
13
14 Provide more information on surgery and rehabilitation

Female 40-49 yrs old – "Perhaps an explanation of what rehabilitation means, I'm not sure I would really know what that means."

15
16
17
18 **Health professionals**

19 Modify the presentation of the two surgical options [GP]

GP, Female 30-39 yrs old – "I wonder in the surgery part, the box that has subacromial decompression and rotator cuff repair, if it would be easier to just have it listed as two hot points instead of two separate columns."

20
21
22
23
24 List non-surgical options first [PT/CP/OS]

OS, Male 40-49 yrs old – "Usually when we're talking about treatment...we're mentioning no surgery first. I think therefore that should be put first instead of having surgery first because it doesn't make sense to talk about surgery first when I'm seeing a patient."

25
26
27
28 **Modify the formatting or**
29 **graphics**
30

31 **Patients**

32 Improve the graphics (e.g. current image makes it appear
33 surgery is less invasive than it is, current image of surgery too
34 graphic, remove clock image, put image of person doing
35 exercise on the left so it stands out more)

Female 50-59 yrs old – "You might want to fine tune that one picture...is there another one you can put that's not so harsh?"

36
37 Improve the formatting of surgical options (e.g. list
38 procedures side by side, highlight procedures in a different
39 colour, put a clear dividing line or increase space between the
40

Male 20-29 yrs old – "Potentially on the first page you could have subacromial on the left and rotator cuff on the right to have continuity in that sense."

procedures, list surgical options before non-surgical options due to previous positive experience with surgery, replace '12 weeks' rehabilitation with '3 months' rehabilitation)

Re-word or re-format this section

Female 40-49 yrs old – "Again a small thing, the underlining probably needs to finish next to the full stop."

WHAT ARE THE LIKELY BENEFITS OF SURGERY COMPARED TO NON-SURGICAL OPTIONS?

Health professionals

Positive feedback

Icon array, statistics, footnotes and colour scheme are clear and appropriate [PT/CP/GP/OP]

OP, Female 40-49 yrs old – " I think the description is really quite good and that's the sort of language that I would usually use to describe what's happening as well."

Patients

Key messages box, bar graphs, icon array, description for certainty of evidence, explanation of placebo and formatting is appropriate

Female 60-69 yrs old – "I think the layout is good, when I read this it seemed simpler too."

Health professionals

Revise description for the certainty of evidence

Remove the description of the certainty of evidence [PT/OS]

OS, Male 40-49 yrs old – "So we're trying to teach patients how to interpret correct evidence and that is a hard thing to do."

Using green font for high-certainty evidence will drive patients towards surgery [PT/CP]

CP, Male 20-29 yrs old – "Some people might interpret the high certainty evidence as a better thing, but when you actually read it, subacromial decompression is little to no better than placebo."

Describe certainty of evidence as 'strong' instead of 'high-certainty' [PT]

PT, Male 40-49 yrs old – "I would drop the certainty and figure out another adjective or just 'strong' evidence, something like that, maybe a stronger word that's one word or two words. Low moderate is confusing."

Health professionals

	Evidence doesn't match experience (e.g. careful patient selection will yield better outcomes) [OS/GP]	GP, Male 50-59 yrs old – "If you select the patient well enough often the result is not as bad as 3 percent, probably significantly higher."
	Evidence from Cochrane reviews may not be generalizable to patients [OS]	OS, Male 40-49 yrs old – "We don't really want to generalise the patient's condition because some patients may have pain that's caused by a specific problem that doesn't fit in with what these studies were looking at."
Evidence doesn't match experience, more clarification needed	Highlight that surgery may increase the speed of recovery or yield better long-term outcomes [OS]	OS, Female 50-59 yrs old – "I agree that at 12 months you're probably the same as if you didn't have surgery, but what's the patient journey in that 12 months between the two groups? That doesn't come out in this. So if the surgical group are sleeping and are back at work and are comfortable sooner then that's relevant."
	Acknowledge that statistics represent averages and individual results may vary [GP/OP]	OP, Female 40-49 yrs old – "[Suggested to write] 'Some patients report a better result than these statistics would show but plenty don't' ...or something like that."
	Add outcomes or provide further explanation for existing outcomes (e.g. include quality of life, define treatment success, emphasise pain results) [GP/PT/OP]	PT, Female 30-39 yrs old – "They fix what's inside and they might get range, but their pain is still ongoing and that was the reason they wanted the surgery in the first place."
	Mention the population and time points of the evidence [PT/CP/OS]	PT, Male 30-39 yrs old – "I know a lot of people would, especially in layman's terms, read this and say 'well that doesn't apply to me, I could heal better than that or it wouldn't affect me.' It might be nice to put the patient population in these two studies just so people can say oh cool, it was mostly older people or mostly younger people. "
	Appears negative towards surgery but agrees the statistics are supported by evidence [PT/OS]	OS, Female 50-59 yrs old – "If they're cut and paste from a Cochrane review then that's the best evidence

that we've got so we can't dispute it, I just don't like it."

Highlight that surgery may be useful for preventing tears progressing even if there was no improvement in symptoms [OS]

OS, Male 40-49 yrs old – "In that group, a single tendon tear has become a one and a half to a two tendon tear, so the acute component which is just a tear has extended to involve the next adjacent tendons. I don't think that's covered well by any study."

Emphasise the uncertainty of the statistics [OS]

OS, Male 50-59 yrs old – "I think using 'somewhat confident' is an overstretch...the literature presents many unknowns...that's why there's a strong need for better studies."

Health professionals

Avoid numeric estimates (e.g. 3% could be framed as 'small') [PT]

PT, Female 30-39 yrs old – "I'd even take out the numbers and just have "on average surgery has less pain and better function but not by much" or something."

Replace bar graphs with a 'key messages' box [PT/CP]

CP, Male 20-29 yrs old – "I do like those boxes, I think that's probably even a little bit more helpful than the bar graphs themselves."

Choose one way to summarise the data (e.g. bar graph or key messages box but not both) [PT/OS]

PT, Male 40-49 yrs old – "I think as a patient you might lose somebody...a lot of numbers and words together and graphs, that's a lot, it's a busy slide or it's a busy section, and they're both together so it's a lot of information on both sides."

Repetition of evidence is biased against surgery [OS]

OS, Female 50-59 yrs old – "I think you need either the chart or the box or one of them, but all three to me is just repetition saying "don't have surgery", "don't have surgery", "don't have surgery.""

Statistics might be hard for patients to understand [PT/GP/OS]

GP, Female 30-39 yrs old – "I think they would expect that it's a yes or no answer, we know it or we don't."

Simplify the statistics

bmjopen-2021-054033 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/> by copyright.

	Difference between surgeries might be hard for patients to understand [PT/CP]	PT, Male 20-29 yrs old – "Again it's like do they really know the difference between rotator cuff repair, subacromial decompression?"
	Include the same comparison group when describing the evidence for both surgeries (e.g. remove placebo comparison) [PT/CP/OS]	CP, Male 20-29 yrs old – "I don't think people really understand the concept of placebo surgeries, that seems super weird to some people when I've told them about that... maybe just [say] "subacromial decompression doesn't seem to be better than some of the other options in terms of changes in pain and function.""
	Re-word the certainty of evidence statement [PT]	PT, Male 30-39 yrs old – "I'm wondering if there's a different way to phrase that, we are very certain, that almost seems like it's an ad on a TV or something. I think that maybe "we are confident in these results as these were high quality studies" or something like that."
	Patients	
	Provide information on the source of the evidence	Female 50-59 yrs old – "Then you get this percentage, I don't know how you got this percentage."
	Provide more explanation about the certainty of evidence	Female 60-69 yrs old – "When you say this research on surgery is high quality, I wouldn't know what low quality is."
Provide more detail or revise the description of the evidence	Including both the 'key messages' box and icon array is confusing	Interviewer – "What about the percentage of people reporting treatment success in the four with the green and grey people?" [icon array for benefits that was removed]
	Adding the age range of research participants is not necessary unless being outside this range would influence the benefits of surgery	Male 20-29 yrs old – "So is that coming out of a different set of research?" Male 20-29 yrs old – "I'm 20. I'm not sure if there would be anything different on younger people. Even

		the ages of the participants, I'm not sure if that really changes it."
	Provide more detail on the non-surgical comparison groups	Female 40-49 yrs old – "I guess under subacromial decompression surgery you haven't given any alternatives to surgery, whereas under the rotator cuff repair you've given alternatives to surgery, so the injections, physiotherapy etc. Would those alternatives apply to both?"
	Clarify whether the evidence applies to those with severe pain	Male 20-29 yrs old – "I know it's very difficult to do, but if there was some table about scales of pain and severity of injuries, as to whether you should be going for surgery or non-surgery therapies."
	Patients	
	Clarify that numeric estimates are averages and that some people will experience better or worse outcomes	Male 30-39 yrs old – "I think that's important because I need to know what the average outcome is and then I can then speak to my GP or surgeon or someone to find out if my particular case is likely to be better than average or worse than average."
Contextualise the evidence to reflect uncertainty on an individual level	Emphasise that surgery may help but it will not be a cure	Male 40-49 yrs old – "It will help but it's not perfect. I guess that would probably be more relevant than stats about success"
	Statistics shouldn't influence treatment decisions as they are averages and patients should trust their health professional's advice	Male 40-49 yrs old – "The stats would not come into it for me at all. The stats are obviously for a large selection of the population, that's an average, it doesn't necessarily apply to my specific situation. So if it was determined by a health professional or medical professional that I needed surgery I'd just take it, the stats would not be a consideration whatsoever."
	Health professionals	
Modify the formatting or language used	Mention the findings before the certainty of evidence [CP]	CP, Male 20-29 yrs old – "So starting off with 'subacromial decompression is little to no better than

bmjopen-2021-054032 on 30 August 2021 by guest. Protected by copyright.

	placebo' and then following it up with there's high certainty evidence for this."
Shorten the 'key messages' box and include other information as footnotes [GP]	GP, Female 30-39 yrs old – "I like the version two where it's a smaller box there and it's cut out some of the text and put it below as well."
Make the bar graphs vertical [PT/CP]	CP, Male 20-29 yrs old – "I think that would make sense to a lot of people. Maybe even just going in a vertical sense might also help some folks but I don't think there's too much trouble with that."
Modify the colour scheme and presentation [PT]	PT, Female 40-49 yrs old – "I was just wondering if you could change the colour of different procedures so that they can see more difference."
Reduce the amount of text [PT/OS]	OS) Male 40-49 yrs old – "I think the second page, the likely benefit is just a bit wordy. I think a patient will get to that and just think, ugh, they will probably just be captured by the green men [icon array which was later remove]
Patients	
Shorten 'key messages' box and include other information as footnotes	Male 30-39 yrs old – "I think having a smaller box and just having these couple of points...makes it quicker to read to get the basic information and the important information."
Limit footnotes as they slow the reading pace	Male 30-39 yrs old – "Almost every single line you're going back down and then you're going back up. It's really not easy, it doesn't flow well and it's not easy to read that."
Suggested strategies to reduce text (e.g. not repeating information in each column, move some information to a 'further reading' section, replace words with graphics)	Male 20-29 yrs old – "A lot of text, I'm wondering if you could make it more infographic...I mean the boxes are good if you read it, but again I'm wondering if you can make it more easily digestible from a picture?"

Icon array is not useful (e.g. confusing, prefers bar graph, icon array takes focus off key messages)	Male 30-39 yrs old – "I'd probably just neg all this and go straight to the bar thing...condense it all down, crack on, it's just too much words and too much extra stuff."
Address inconsistency between headings, figures and text	Male 20-29 yrs old – "Are those first two really benefits?" [highlighting that there are actually no benefits of surgery]
Mention benefits before harms as benefits are the crux of the decision aid	Female 40-49 yrs old Williams – "I was just thinking about the order starting with complications and then going to benefits, you normally would see it the other way around."
Numeric estimates, surgical options and footnotes are confusing	Male 60-69 yrs old – "Subacromial decompression surgery, what does that mean?"

WHAT ARE THE LIKELY HARMS OF SURGERY?

Health professionals

Presentation of harms is appropriate [PT/OS/OP]	PT, Male 30-39 yrs old – "Again, they're simple, graphic and visual, easy to read and certainly makes you reconsider surgery, so yeah that looks good."
---	---

Patients

Positive feedback

Clear figures and text which would make patients think hard before having surgery	Female 40-49 yrs old – "I think the image is useful there actually"
Statement about the risk of harms being higher in people with other health conditions is valuable	Male 30-39 yrs old – "The serious problem one, it's possible it might deter me, but not that much. It would depend obviously on my personal condition and my personal scenario...then I can tell if I'm one of those average people, or if I'm better or worse than the average person...I think that's nice and clear, I can get a lot of information out of that quite quickly."

Health professionals

	Distinguish between surgical complications, complications specific to the procedure (e.g. frozen shoulder) and poor outcomes [GP/OS/PT/OP]	OP, Female 40-49 yrs old – "Harm is different to unsuccessful outcomes so again, they have to be separated out."
	Mention revision surgery as a possible adverse event [OS]	OS, Male 40-49 yrs old – "So discussion about the need for re-do surgery is usually about poor healing... What I'm talking about there is failure of repair. There are other needs to do revision surgery when the repair has healed well but, for example, the patient may have a recalcitrant adhesive capsulitis or frozen shoulder."
Present minor and serious harms	Patients	
	Important to know both minor (e.g. loss of movement and strength) and serious harms	Male 30-39 yrs old – "Recovery time would be very important to me in a trade. Probably if there's other side effects as a possible loss of range of motion or strength because that would severely impact my work and day to day life."
	Definition of minor and serious adverse event is problematic because severity is subjective	Male 30-39 yrs old – "Saying a serious problem versus a non-serious problem, I think that's very relative to the patient because that becomes a material assessment."
Provide more context for harms	Health professionals	
	Presenting harms in a different section to 'benefits' doesn't give an understanding of harm vs. benefit [GP]	GP, Female 60-69 yrs old – "When you compare them [harms] to the benefits being very minimal, then the harms outweigh the benefits...the graphics don't really show that aspect."
	Compare the harms of surgery and non-surgical options [PT/CP]	CP, Male 20-29 yrs old – "One in one hundred people who are going through something like this, that's big. We look at rates of adverse reactions in manual therapies, you're looking at like 1 in 3 million."
	Patients	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Presenting harms in a different section to ‘benefits’ doesn’t give an understanding of harm vs. benefit

Interviewer: If it did get to a point where you needed to consider that [surgery], what would you most want to know while you’re weighing up that choice.

Male 30-39 yrs old – Probably the risks involved and the chance of success in comparison to that risk.

Emphasise surgery involves a general anaesthetic

Female 60-69 yrs old – "Again you’ve got to count into that anaesthetic, do I really want to go under anaesthetic for it as well?"

Health professionals

Harms might be overestimated [OS]

OS, Male 40-49 yrs old – "I would say deep infection in my practice, and having done arthroscopic surgery for more than 10 years, it might be 1 in 10,000. That doesn’t relate to me in my practice, so I wouldn’t give my patients those statistics."

Harms might be underestimated [PT]

PT, Female 30-39 yrs old – “My only other feedback is about the harms of arthroscopic surgery. I would look at that and think ...it’s not likely I’m going to be having any problems... 1 in 100 makes it look like it’s not that likely but actually 1 in 100 is quite high.”

Highlight populations who are at the greatest risk of harms (e.g. diabetes, other co-morbidities) [CP]

CP, Male 20-29 yrs old – "I know it takes up more space to add more information always, but letting them know or saying predisposing risk factors for serious problems or for frozen shoulder, comorbidity conditions, if any."

Health professionals

Format the harms section so it is consistent with the benefits section [PT]

OS, Male 40-49 yrs old – "Yeah, and present them in the same way. Whatever format you choose."

Move harms to practical issues section [CP]

CP, Male 20-29 yrs old – "So going back to what you were saying, what do we use for visuals, tables are probably really good. This [presenting harms in practical issues section] is just another way of showing

Evidence doesn't match experience, more clarification needed

Modify the formatting or language used

bmjopen-2021-0540332 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

the difference, this might even be another way when we're comparing the harms of arthroscopic surgery versus conservative care that might even be another way to compare the two so people can see."

Include in-text citations or state 'figures are from the most up to date medical research' [PT/CP]

CP, Male 20-29 yrs old – "To say that it's based on the most up to date medical evidence is probably really important."

Replace 'harm' with a less emotive word (e.g. 'risk', 'complication') [OS]

OS, Female 50-59 yrs old – "So this one I found even more emotive harm is in red and underlined... I wonder if there might be a different word, I know you're avoiding risks, you're using the word harms rather than risks, I don't know what other word might be better. "

Re-format to emphasise the harms (e.g. place minor harms on the left side of the page as they are most important, icon array downplays the true risk of harms)[PT]

PT, Male 20-29 yrs old – "Maybe with this graphic because the percentage is so small, it takes up a lot of space to do that. I guess it can be a good graphic to show how if you look at this you'd think I'd be pretty unlikely to get a problem is what you take away from that. The graphic does its job but if you think there's only half a person getting a serious problem that's probably not going to be me."

Patients

Change the terminology used (e.g. 'harms' too negative, change 'harms' to 'risk', change 'person' to 'people', define 'frozen shoulder')

Male 40-49 yrs old – "'Harms' seems dangerous. I suppose I think risk is inferred with those kinds of procedures. I'm just thinking there's maybe a better word than harm."

Change the formatting of numeric estimates (e.g. keep the same denominator for minor and serious adverse events, use 6 in 1000 rather than <1 in 100, use 4% instead of 4 in 100, remove icon array to save space, avoid text touching the boxes, seek help from a graphic designer)

Male 20-29 yrs old – "I don't know how much the picture does for me, if you just had a big 4% there that might get the same message across."

bmjopen-2021-054033, 2021, Downloaded from <http://bmjopen.bmj.com/> on 11 December 2022 by guest. Protected by copyright.

SUMMARY OF BENEFITS, HARMS, AND OTHER PRACTICAL ISSUES

Health professionals			
Positive feedback	The whole section is appropriate [GP/PT/OS/OP]	PT, Female 30-39 yrs old – "I like the idea of the table at the end about the practical issues that they should consider."	
	Being vague about costs is appropriate because as patients in the public system may not have any out-of-pocket costs [PT]	PT, Female 30-39 yrs old – "I feel like that's why so many people go surgically as opposed to going along a conservative physiotherapy driven pathway, because they've got to pay privately for physiotherapy and injections but they get their surgery done for free at the hospital and then will often go into the public system for their rehab as well."	
	Patients		
	Content, layout, and discussion about costs and recuperation after surgery is appropriate	Male 40-49 yrs old – "I'm looking at them through a different lens this time and I think they're pretty much spot on."	
	Global summary would be helpful for people without time to read the entire decision aid	Female 70-79 yrs old – "I think that it's very good. Some people who won't read through things. This is so neat and tidy and it takes you a minute or so to read."	
Health professionals			
Revise information on costs	Include the cost of non-surgical options (e.g. time, effort, cost without insurance coverage) [CP]	CP, Male 20-29 yrs old – "If this is just somebody paying out of pocket because they have shoulder pain it might actually be more expensive for them to seek care from a physio or a chiro than it would be to just go get a surgery because that's going to be covered through their insurance."	
	Be specific about costs to emphasis the true cost of surgery [PT/GP]	GP, Female 30-39 yrs old – "I think [include] the actual cost itself, which is very hard for you to put in a decision aid. I know depending on which area, which	

		surgeon, it could be very different, but just giving an idea of how much these costs are."
	Include costs related to time off work [OS/PT]	OS, Male 40-49 yrs old – "Out of pocket costs, correct, there's the other costs are not working, so if someone has used up their sick leave, whether it's surgery or no surgery, then they're on leave without pay so that's another cost to consider as well."
	Soften the language emphasising the costs of surgery [OS]	OS, Male 50-59 yrs old – "When you say the out of pocket costs for surgery are generally high, I think that's a value statement. I would say they are generally higher than non-operative treatment. Some surgeons don't charge anything, there's no out of pocket paying cost for some patients."
	Patients	
	Be more specific about costs (e.g. time off work, add "speak to your GP and insurance provider to understand exact costs", costs of non-surgical options, non-surgical options might equally expensive in some countries)	Male 70-79 yrs old – "How much is going to cost in the hospital? Am I covered by medical benefits? How much am I covered for my medical benefits? How long am I going to be in hospital? What are the charges?"
	Highlight that waiting times are long and costs are higher without private insurance	Male 30-39 yrs old – "What I want to do and other factors, financial factors as well and how long I have to wait for the sort of stuff, all these things."
	Health professionals	
Revise information on activity restrictions and post-surgical management	Revise timeframes for post-surgical activity restrictions [OS/PT]	OS, Male 50-59 yrs old – "Practical issues after decompression, I would suggest avoiding heavy lifting usually for six for twice that long, that's a bit short. They may elevate above their head at 1-3 weeks but we would not let them heavy lift for 6-8 weeks."
	Include timeframes for returning to normal function (e.g. sports, activities of daily living, pre-injury function) but also acknowledge the possibility patients won't return to normal [PT/CP]	PT, Male 30-39 yrs old – "I guess that's what people want to know - will I be able to play, pick up ball again."

1 2 3 4 5 6 7 8 9 10	Highlight that symptoms may improve, with or without surgery [GP]	GP, Female 30-39 yrs old – "No recuperation time frame, it makes it sound like with surgery you will just always have symptoms whereas without surgery you won't have symptoms. I understand that is correct, I'm trying to say, symptoms may come and go until rehabilitation is completed? I don't know how to word that."
11 12 13 14	Mention that people who do not have surgery will still have their usual symptoms and their improvement will depend on the success of the non-surgical options they try [OS]	OS, Female 50-59 yrs old – "If you don't have surgery there's no surgery to recuperate from, but you still have your primary symptoms, so you're not pain free."
15 16 17 18	Emphasise that symptoms will get worse following surgery due to the procedure [PT/OS]	PT, Male 30-39 yrs old – "It seems a lot of people don't fully conceptualise that, you can't even use the muscles in your shoulder for 6 weeks. That's a pretty big consideration."
19 20 21 22 23 24	Add a row for 'social support' (e.g. getting dressed, dishes, transport to appointments) [PT]	PT, Female 30-39 yrs old – "The other thing I would put in there is people getting to rehab if they don't have someone social support. Who's going to help them get dressed or do their dishes, take them to appointments."
25 26 27 28 29 30 31	Highlight that people must do exercises following surgery [PT/OS/CP]	OS, Male 40-49 yrs old – "I tell them that their shoulders will be stiff and will have deconditioned because they've been waiting for their tendons to heal and the structures to heal. It usually takes that extra 3 months of work to rehabilitate them enough that they can get back into manual labour type activities."
32 33 34 35	Define 'heavy lifting' [PT]	PT, Female 30-39 yrs old – "I think I'd try to be a little more specific with that, because heavy lifting is so specific to different people."
36 37 38 39 40 41 42 43 44 45 46	Include activity restriction timeframes for non-surgical options [PT]	PT, Male 30-39 yrs old – "Do you have anything in there for 'no surgery' as well, like most people do well in 6 weeks or expect 12 weeks?"

Highlight that recovery is influenced by the severity of a patients' pre-intervention symptoms [OS]

OS, Male 50-59 yrs old – "I think just recognising that there is a spectrum of severity of symptoms, that they're not all the same. Therefore, people with lower symptoms are generally more likely to improve."

Patients

Emphasise driving restrictions

Male 70-79 yrs old – "I would rather see 'you can't drive for 6 weeks' rather than 'you can.'"

Emphasise that patients may need treatment after surgery (e.g. physiotherapy, injections, exercise, etc.)

Male 40-49 yrs old – "I guess my experience is even after surgery there's still lots of injections, lots of medication..."

Highlight the need for patients to consider their individual circumstances before making any decisions (e.g. pain levels, social aspects, insurance, job demands, caring responsibilities, age, activity levels, sports participation, etc)

Male 40-49 yrs old – "I think that's probably a lot more important to consider with stats; where would you be without this if you can't go back to doing the things you want to do again? In another non-sporty point, if it affects a tradesman ability to earn income it affects their entire family's quality of life. So I think that's probably the more responsible point to make in it, rather than you'll get 9 or 6% less pain and that sort of stuff."

Add a column for 'no treatment'

Female 60-69 yrs old – "Are you allowed to have a column that says 'no treatment?'"

Health professionals

Separating practical issues by type of surgery results in too much information [PT]

PT, Male 20-29 yrs old – "Do they really know the difference between rotator cuff repair, subacromial decompression? I guess it's really only if they've been told that's what appropriate for them that they then go, which one are I?"

Split the practical issues section by type of surgery [GP]

GP, Female 30-39 yrs old – "Then the third page I guess the text looks like instead of lines we split something into two columns."

Discuss 'Follow-up with surgeon' in 'Recuperation' section [GP]

GP, Female 30-39 yrs old – "Maybe talk about the follow up in recuperation. I think that suits

Modify the formatting or language used

anyway because it automatically presumes that I have private health insurance or that this is a work cover thing. It makes an assumption of the reader."

Acknowledge that timeframes are averages so patients don't get disheartened when they don't reach a milestone on time	Female 50-59 yrs old – "If you just say an average and you don't hit that 21-day average- unfortunately whatever affects your body affects your mind."
Change the colour of table to match other sections of the decision aid	Female 40-49 yrs old – "This table is quite clearly laid out...good use of shading and colour, although the blue is a different shade to what's used in the whole rest of the leaflet."

QUESTIONS TO CONSIDER WHEN TALKING WITH A HEALTH PROFESSIONAL

	Health professionals	
	All questions are important [GP/PT/OS/OP]	OP, Female 40-49 yrs old – "I think that's really good because you can tick through that and make sure that they've understood the really important points."
	Patients	
Positive feedback	All questions are important	Male 20-29 yrs old – "Especially the last one [about] information and support. I think that's often one that I've seen some of my friends sometimes don't [ask]. So I think that's an amazing one to have in there."
	Agrees that patients should be directed to ask questions	Female 20-29 yrs old – "I think they're good because when you're in an appointment setting for me I get really nervous and I don't always think."
	Health professionals	
Adding and removing questions	Add questions (e.g. "Do I understand what's wrong with my shoulder?"; "What level of activity can I get to if I have surgery versus not?"; "How much non-surgical management should I try before considering surgery?") [OP/PT/OS]	PT, Male 20-29 yrs old – "If I wait with my tear, is that going to mean it keeps tearing and then I need surgery later on and it gets worse?' that sort of thing."

Remove questions (e.g. "Do I know enough about my condition"; "Have I considered my individual circumstances") [OS]

OS, Male 40-49 yrs old – "I don't think that's a good question to ask because you're asking the health practitioner to read the patient's mind. 'Have I considered my specific situation?' Again, that's not something a health professional can answer in that format."

Patients

Add questions (e.g. "Can I have surgery later?"; "What is my diagnosis? Are there any other surgeries performed for this type of shoulder pain?"; "What other treatment options do I have/who else can I see?"; "How will my individual circumstances impact me?"; "What happens if I don't do anything?")

Male 20-29 yrs old – "Maybe add in there 'what is my diagnosis.'"

Health professionals

Increase the size of this section [PT/CP]

PT, Female 30-39 yrs old – "Can we make the 'other things that I can do 17 times bigger?' I almost think that box 'other things I can do' needs to be up there on that first page under no surgery."

Could replace "Questions to consider when talking with your doctor" section with "Any further questions, ask your doctor" to save space [GP]

GP, Female 30-39 yrs old – "If you needed to cut that out, I would cut out and say any 'further questions talk to your doctor.'"

Modify the formatting

Change the heading of this section so it applies to any health professional [PT]

PT, Male 20-29 yrs old – "Then the 'questions when talking to your doctor' are what we were saying before for your doctor or physio."

Change the heading of this section so it applies to GPs [PT]

Interviewer – "In which case do you think we need to direct people who to ask these questions to, rather than keeping it open like that? We've just said health professional, knowing that could be a whole number of people. Do you think we should say 'ask your GP', ask your physio or even just subcategories the questions depending on who they're asking."

PT, Male 40-49 yrs old – "Put great faith in GPs, they really care for their patients."

Patients		
	Remove this whole section to create space	Male 20-29 yrs old – "I don't think it adds a lot for me just because I think they're kind of obvious in a sense. I think questions would naturally arise from this."
	Modify the formatting for the bullet points (e.g. words don't line up with the bullet points, too cramped, put questions in speech bubbles)	Female 40-49 yrs old – "In the third one, the spacing of the lettering is quite different to the spacing in the fourth one."
	Change to "Questions to consider when talking with a health professional..." (instead of "your health professional")	Male 40-49 yrs old – "So when I just see the way that heading looks... I'm wondering if that's pointing them too specifically just to one person."
	Combine the first two questions	Male 40-49 yrs old – "Am I clear about the benefits and the harms. That's the same as "Do I know enough about the benefits and harms?"
	Categorise questions based on which health professional should answer them	Male 40-49 yrs old – "I'm wondering if there should just be more specifics around health professionals. I mean they're all health professionals, but some I've found to be more valuable than others."

ARE THERE OTHER THINGS I CAN DO?*

Patients		
Positive feedback	"Other things I can do" box is great (1) [PT/CP]	PT, Male 40-49 yrs old – "So you make up for it by highlighting that which is cool, for saying the ongoing commitments. I like that you're putting that there."
Health professionals		
Modify information to help people choose non-surgical options first	Move this section to the first page and make it clear surgery is a last resort [PT/CP]	CP, Male 20-29 yrs old – "Obviously really good advice, I think that should almost be at the forefront. These are pretty good options that they're probably going to have to try even before considering surgery because ... surgery is often a last resort."

Be specific about what exercises can be done [PT/CP]

PT, Male 20-29 yrs old – "I think in general you hit the broad spectrum of things, from a physical therapy standpoint obviously I might include beyond just strength and endurance exercises, strength, flexibility, endurance exercises."

Emphasise that there is often no need for early surgery and no harms in delaying surgery [OS/PT]

PT, Male 20-29 yrs old – "It was more a fear of 'if I don't do it now then what happens in the future?'"

OVERALL FEEDBACK

Health professionals

The graphics will assist non-English speaking people [PT/OS]

PT, Female 30-39 yrs old – "A lot of my clients don't speak English so I'll always go with pictures and graphics and really easy to understand things."

The decision aid will be an important tool for busy clinicians [PT/OS]

OS, Male 40-49 yrs old – "Assuming that the GPs have some musculoskeletal background and know a little bit about this problem...then having that information sheet [decision aid] certainly is helpful and I can assess the patient, they already know some of that information and I don't have to rehash everything."

Positive feedback

There is no information that is not important in this decision aid [PT/OS/GP]

PT, Male 30-39 yrs old – "Maybe you could take that's the problem it's all pretty useful."

Patients

Language, flow. explanations, content, length, and disclosure statement are appropriate

Male 30-39 yrs old – "That seems fairly straight forward as well, there doesn't seem to be anything in there that I don't either understand or isn't visually represented."

References are important but should be provided on request

Male 30-39 yrs old – "You could maybe just say 'references can be provided via emailing this address.' I don't know if you need to put all those references in there."

bmjopen-2021-054033 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	The decision aid will be an important tool for patients who do not receive enough information in a consultation	Male 40-49 yrs old – "My surgeon, wonderful guy, really nice guy and he's done a great job, he never really explained a lot to me."
Reduce amount of information	Health professionals	
	A 2-page decision aid is ideal [PT/CP/GP]	GP, Female 30-39 yrs old – "I don't know if this is possible, but I think two pages. So being able to... print it double sided and have just one piece of paper given to the patient it feels in my head less overwhelming than a bunch of paper being stapled together and saying here, read it all."
	The decision aid includes too much information [GP/OS/PT]	OS, Male 40-49 yrs old – "I thought it was a bit too busy...there's so much writing now I can't tell. If you're going to give that to the general public you've got to be like it's pretty straight forward."
	Create a simplified version of the decision aid for patients [PT]	PT, Male 20-29 yrs old – "Maybe you give this one to the health practitioner and you do a separate for patients to take with them."
	Remove some sections (e.g. questions to ask a health professional, references, rotator cuff repair surgery) [PT/OS]	PT, Male 30-39 yrs old – "Do the patients care specifically about references?"
More detail needed	Health professionals	
	Include a section on diagnostic imaging (X-Ray, MRI, Ultrasound) and the importance of not missing a serious disease [GP]	GP, Female 60-69 yrs old – "You don't want to miss arthritis or tumours or things like that. I think that would be useful to...understand the roles of each, of the x-ray ultrasound and MRI."
	More detail is needed if the decision aid will be used without input from a health professional [PT]	PT, Male 20-29 yrs old – "I think the one that would be sent home you would want a little bit more detailed versus one that you are with a patient going over it."
	Acknowledge who made this decision aid so patients can evaluate the quality of the information [OS]	OS, Male 50-59 yrs old – "Acknowledge what the background of the people constructing it is..."
	Patients	
	Last page lacks a solution if a patient has tried everything	Male 20-29 yrs old – "I don't know if that exists or not but to give people a new solution."

Encourage people to seek a second opinion or further information

Male 70-80 yrs old – "Do I have enough information and if not what do I do? I guess, if I answer that as no, I don't have enough information, then what do I do next, I've already spoken to the doctor."

Interviewer: That's a good point, maybe some links to further resources might be helpful.

Participant: Yeah."

Health professionals

Improve the colour scheme or layout (e.g. improve consistency, space out information) [GP/PT/OS]

PT, Male 40-49 yrs old – "I feel so critical, it's a bit gloomy."

Create separate decision aids for each procedure [CP/OS/GP]

OS, Female 50-59 yrs old – "It's too much covering decompression and rotator cuff repair on the one handout because they are two separate conditions and they're offered for different reasons and they should be separated."

Create separate decision aids for surgical and non-surgical options [GP]

GP, Female 60-69 yrs old – "Having surgery as a separate one [decision aid], because you wouldn't tell them about [surgery] straight away...I think it's too much information at the beginning, most people would get a bit alarmed if you talked about surgery at the beginning."

Create a video summary of the decision aid [PT/CP]

CP, Male 20-29 yrs old – "I feel like people nowadays don't have a great attention span...I almost wonder if somehow like a video, they could access it on Youtube or something free like that."

Include citations in the decision aid [CP]

CP, Male 20-29 yrs old – "I don't see a citation."

Acknowledge that treatment decisions might be influenced by the health professional the decision aid is discussed with [PT/OS]

OS, Female 50-59 yrs old – "In my experience, those who fail non-surgical do really well with surgery and so most of my patients do better, but I haven't got a

Formatting or distribution suggestions

group to compare them to so I've got a very biased view of surgery because that's all I see."

Distribution suggestions for the decision aid (e.g. in a clinic, early in treatment, when a patient is considering surgery, after a diagnosis is made) [PT/OS]	OS, Male 40-49 yrs old – "The most useful thing that we're talking about surgery vs. no surgery, is at the junction when surgery is being considered and that is in the specialist's office, to me that would make the most sense."
Improve readability of the decision aid [PT/OS]	PT, Male 40-49 yrs old – "I think the challenge with language is, let's say your aim is to get the FKMG score of a reading literacy score down to year 8 or year 6. A message that details enough to be satisfactory for a consumer, but without getting there's a lot of words on this page."
Patients	
Include page numbers	Male 70-79 yrs old – "I kept looking for more pages, only because I thought it would have been a longer thing for no reason other than why won't it go page down anymore. So maybe 'page 1 of 3' or something like that on the top."
Create several decision aids (e.g. one for each surgery, one for patients and one for health professionals)	Male 30-39 yrs old – "It's like half of that is not relevant to me if I have subacromial decompression surgery and the other half is not relevant to me if I have a rotator cuff injury. It's like well give me the one that's relevant for me."
Improve readability (e.g. increase the font size, space out the text even if it means the decision aid is 3 pages, use a consistent design across pages, use a darker grey background)	Male 30-39 yrs old – "I think a lot of the text is too small...I know it's a draft, I just think it's a bit- it doesn't easily flow well."
Patients should read the decision aid before or after a consultation with a health professional so they don't waste a health professional's time and can ask questions	Male 30-39 yrs old – "You have to be able to ask questions to somebody, so a health professional it could be an GP, a physio, a nurse or a doctor...but probably not as a one-on-one, face-to-face thing. It

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
 BMJ Open: first published as 10.1136/bmjopen-2021-025403 on 11 December 2022. Downloaded from http://bmjopen.bmj.com/ on 11 December 2022 by guest. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	would be sitting in the waiting room, “read this, if you have any questions jot a little note, then when you come in ask the questions to clarify””
Remove 'disclosure' section	Male 30-39 yrs old – "That would then take out the whole funding thing as well... You declare that there's no conflict of interest or say nothing to disclose or nothing to declare."
Emphasise the question asking section and de-emphasise others (e.g. harms, causes of shoulder pain, references)	Male 40-49 yrs old – "Yeah, and maybe the very beginning one... “who should read this decision aid”, I think maybe that's too much. I think it's very doctor-y wordy... The very last one [questions section] I think is probably too little... [we need] a little bit of balance with the very last one and the very first one."
Move 'Important information' to above the references so patients are more likely to read it	Male 30-39 yrs old – "It blends in. As I'm coming down the page, if I saw it I would read that. Whereas it gets lost in references straight away."

Health professionals

Suspects bias or questions relevance of the decision aid

Thought the decision aid's underlying goal is to reduce the use of surgery and thought it should be more balanced [OS]	OS, Male 40-49 yrs old – "Really what you're trying to do is get them to not have the surgery."
Believes evidence is changing and the decision aid may become irrelevant overtime [OS]	OS, Male 40-49 yrs old – "I mean that's the current view, and in a year's time that might change."
Unsure of the applicability of the decision aid when patients don't have a diagnosis or when they have tried all the non-surgical options listed [OS]	OS, Male 40-49 yrs old – "The most useful thing that we're talking about, surgery vs no surgery, is at the junction where surgery is being considered and that is in the specialist's office. To me, that would make the most sense. Before that no one knows what's going on, no one's really talking about surgery, there might be hearsay and things like that, there might be guesses, but at that time you may not even have a diagnosis or imaging etc. Often when I see the patients they've already done a few of those conservative measures which have not worked, which is why they're in my

office...I guess if the decision aid is hitting them at the point where surgery vs no surgery, because there's not so much difference in the short to medium term, then it has to be done after the diagnosis is made I think, or surgery is being considered."

	Patients	
Decision aid swayed patients away from surgery	Swayed towards surgery because it might be beneficial (e.g. pain might get worse, small improvements in pain and function might be important for work, the risk of complications gets higher as you age, subacromial decompression might work if someone has tried all other options)	Female 50-59 yrs old – "It's not too bad for me to consider a shoulder surgery yet, but it's also making me think, maybe it's something I should have before it gets too bad."
	Swayed away from surgery (e.g. would only have surgery if it was a guaranteed solution as time off work and cost is a major inconvenience)	Female 40-49 yrs old – "To me you read that and think, I'm probably not going to go down that route."

CP: chiropractor; GP: general practitioner; PT: physiotherapist; OP: osteopath; OS: orthopaedic surgeon.

*: this section was removed from the decision aid to save space so we could provide more detail about non-surgical options on the first page.

Supplementary File 9. Reasons for not implementing feedback for each section of the decision aid.

Themes	Sub-themes	Reason for not implementing feedback
WHO SHOULD READ THIS DECISION AID?		
Improve clarity on the target population	Health professionals Make the information more specific to a diagnosis [OS/PT]	Identifying a structural nociceptive cause of subacromial impingement syndrome is not possible, so we decided to keep the diagnosis broad (i.e. subacromial impingement syndrome)
	Patients Make it clear the decision aid is for people with subacromial impingement syndrome (e.g. include the diagnosis in the title)	Opposing feedback to remove the term 'subacromial impingement syndrome'
Revise the causes and symptoms of shoulder pain	Health professionals Clarify that shoulder pain can be caused by overuse and work (e.g. heavy lifting) [GP/PT]	Potential causes of shoulder pain were removed as they were too speculative
	Patients Describe what causes the structural issues associated with shoulder pain (e.g. explain why a tendon tears or a bursa gets inflamed)	This information would have been too speculative due to a lack of evidence on this issue
Use positive messaging	Health professionals Language will cause fear among patients [CP/PT]	Opposing positive feedback from patients on our explanation of shoulder pain
	Include positive messaging about prognosis and what pain means (e.g. pain doesn't equal damage, pain may get better with time, imaging findings are common in people without symptoms) [CP/PT/OP]	Beyond the scope of this decision aid
Make this section more concise and relevant	Health professionals Explanation of shoulder symptoms might be irrelevant for patients [GP/OS/PT]	Opposing positive feedback on our explanation of shoulder symptoms
	Graphic of pain distribution might be more useful than a graphic of the shoulder anatomy [OS/PT]	Opposing positive feedback on our graphic of shoulder anatomy

WHAT ARE THE TREATMENT OPTIONS COVERED IN THIS DECISION AID?

	Health professionals	
	Need a flowchart of non-surgical options [PT]	Opposing positive feedback on the layout of non-surgical options
	Highlight how long patients should try different non-surgical options before surgery [GP/PT]	There is no evidence to guide timeframes on trying various non-surgical options. This could depend on treatment success and patient preferences
	More detail is needed on muscle strengthening programs [PT]	Beyond the scope of this decision aid
	Include evidence for non-surgical options [PT/OS]	This decision aid was developed for people considering surgery. We only included one treatment decision (i.e. surgery vs. non-surgical options) and hence, the evidence for surgery compared to non-surgical options
Include more detail on non-surgical options and how to progress management	Patients	
	Provide more non-surgical options	Opposing positive feedback that our decision aid covers all potentially valuable options
	Provide evidence for various non-surgical options (e.g. options listed in the decision aid, lifestyle change, TENS, ultrasound, hydrotherapy, massage, diet, acupuncture, Chinese herbs)	This decision aid was developed for people considering surgery. We only included one treatment decision (i.e. surgery vs. non-surgical options) and hence, the evidence for surgery compared to non-surgical options
	Highlight whether delaying surgery or non-surgical treatment is harmful or not	There is not enough evidence to address this issue. We suggested patients ask a health professional the following question: "Can I have surgery later? If so, how long should I wait before considering surgery?"
	Provide more information on 'wait and see' (e.g. highlight that you can trial non-surgical options while you 'wait and see')	Opposing positive feedback on the description of non-surgical options
Change the non-surgical options presented	Health professionals	
	Inappropriate to mention medication and injections as options [PT/CP]	Cochrane reviews on treatments for subacromial pain syndrome show glucocorticoid injections are superior

		to placebo and provide similar effects to non-steroidal anti-inflammatory drugs (22) and physiotherapy-delivered treatments (e.g. exercise, manual therapy, electrotherapy) (23, 24)
	Mention the benefits of ultrasound for diagnosis and guiding injections [GP]	Beyond the scope of this decision aid
	Waiting 6 months might be too long for patients to do nothing [PT/OP]	Opposing positive feedback on the description of non-surgical options
	Order of non-surgical options might be inappropriate [CP/PT]	Opposing positive feedback on the order of non-surgical options
Include indications for surgery	Health professionals	
	Highlight that imaging findings in isolation aren't indications for surgery [PT/OS]	Peripheral to the main purpose of this decision aid
	Important for patients to know which procedure they are most likely to receive as this could influence recovery and rehabilitation needs [OS]	Too dependent on an individual's symptoms
	Highlight that surgery may improve symptoms or anatomy but not address the cause [PT/OS]	Adding this information might be considered biased against surgery as non-surgical options might also not address the cause of symptoms
Present evidence of benefits or harms in this section	Health professionals	
	Mention the success rate of surgery and non-surgical options [GP/PT/OS]	We only included data on pain and function from the two Cochrane reviews of shoulder surgery. Including findings from responder analyses would have conflicted with feedback to avoid repetition of statistics
	Emphasise the harms of surgery [PT/CP/GP]	Adding this information would be biased against surgery. The presentation of benefits and harms in decision aids need to be balanced
Change information on surgery	Patients	
	Provide less information on surgery	Opposing positive feedback on the level of detail about surgery

BMJ Open: first published as 10.1136/bmjopen-2021-054033 on 11 December 2021. Downloaded from <http://bmjopen.bmj.com/> on December 11, 2023 by guest. Protected by copyright.

Provide more information on surgery and rehabilitation

Opposing positive feedback on the level of detail about surgery and rehabilitation

WHAT ARE THE LIKELY BENEFITS OF SURGERY COMPARED TO NON-SURGICAL OPTIONS?

Revise description for the certainty of evidence	Health professionals Remove the description of the certainty of evidence [PT/OS]	Opposing positive feedback for acknowledging the certainty of evidence
Evidence doesn't match experience, more clarification needed	Health professionals Evidence doesn't match experience (e.g. careful patient selection will yield better outcomes) [OS/GP] Evidence from Cochrane reviews may not be generalizable to patients [OS] Highlight that surgery may increase the speed of recovery or yield better long-term outcomes [OS] Add outcomes or provide further explanation for existing outcomes (e.g. include quality of life, define treatment success, emphasise pain results) [GP/PT/OP] Highlight that surgery may be useful for preventing tears progressing even if there was no improvement in symptoms [OS]	We did not change the evidence presented because it is vital numeric estimates of benefits and harms in decision aids are based on the highest quality available evidence (15, 27) We limited outcomes to pain and function from the two Cochrane reviews of shoulder surgery to avoid repetition We limited the potential benefits of surgery to data presented in the two Cochrane reviews of shoulder surgery
Simplify the statistics	Health professionals Avoid numeric estimates (e.g. 3% could be framed as 'small') [PT]	Opposing positive feedback on the presentation of numeric estimates
Provide more detail and clarify the evidence	Patients Adding the age range of research participants is not necessary unless being outside this range would influence the benefits of surgery	Opposing feedback to mention the population of the evidence
Contextualise the evidence to reflect uncertainty on an individual level	Patients Statistics shouldn't influence treatment decisions as they are averages and patients should trust their health professional's advice	We did not change the evidence presented because it is vital numeric estimates of benefits and harms in

decision aids are based on the highest quality available evidence (15,27)

Modify the formatting or language used	Health professionals Make the bar graphs vertical [PT/CP]	We removed the bar graphs due to negative feedback
WHAT ARE THE LIKELY HARMS OF SURGERY?		
Present minor and serious harms	Health professionals Mention revision surgery as a possible adverse event [OS]	Not a direct harm of surgery
	Patients Definition of minor and serious adverse event is problematic because severity is subjective	Opposing feedback to separate minor and serious harms
Provide more context for harms	Health professionals Compare the harms of surgery and non-surgical options [PT/CP]	Data on the potential harms of non-surgical options was not available
Evidence doesn't match experience, more clarification needed	Health professionals Harms might be overestimated [OS]	We did not change the evidence presented because it is vital numeric estimates of benefits and harms in decision aids are based on the highest quality available evidence (15,27)
	Harms might be underestimated [PT]	
Modify the formatting or language used	Health professionals Move harms to practical issues section [CP]	Opposing feedback to use the same format when presenting benefits and harm
	Replace 'harm' with a less emotive word (e.g. 'risk', 'complication') [OS]	'Harm' is a more accurate term than 'risk' and is used more frequently in the decision aid literature
	Patients Change the terminology used (e.g. 'harms' too negative, change 'harms' to 'risk', change 'person' to 'people', define 'frozen shoulder')	'Harm' is a more accurate term than 'risk' and is used more frequently in the decision aid literature
SUMMARY OF BENEFITS, HARMS, AND OTHER PRACTICAL ISSUES		
	Health professionals	

	Include the cost of non-surgical options (e.g. time, effort, cost without insurance coverage) [CP]	Costs vary too much to include an accurate figure
	Be specific about costs to emphasis the true cost of surgery [PT/GP]	
Revise information on costs	Patients	
	Be more specific about costs (e.g. time off work, add "speak to your GP and insurance provider to understand exact costs", costs of non-surgical options, non-surgical options might equally expensive in some countries)	Costs vary too much to include an accurate figure
	Highlight that waiting times are long and costs are higher without private insurance	This might not apply to all health systems
	Health professionals	
	Add a row for 'social support' (e.g. getting dressed, dishes, transport to appointments) [PT]	Information mostly covered already
Revise information on activity restrictions and post-surgical management	Include activity restriction timeframes for non-surgical options [PT]	Activity restriction timeframes varied by health professional too much
	Highlight that recovery is influenced by the severity of a patients' pre-intervention symptoms [OS]	Suggestion was not relevant to this section
	Patients	
	Emphasise driving restrictions	Driving restriction timeframes varied by health professionals too much
	Add a column for 'no treatment'	'No treatment' is covered in the 'non-surgical options' column
	Health professionals	
Modify the formatting or language used	Separating practical issues by type of surgery resulted in too much information [PT]	Opposing feedback to separate practical issues by type of surgery
	Split the practical issues section by type of surgery [GP]	
	Could use a checkbox to reduce the number of words in the 'Activity restrictions' section (e.g. sling (tick); 3-4 weeks off work (tick), etc.) [CP]	Opposing positive feedback on the layout of this section

	Change title of this section to "What will my recovery look like after surgery and non-surgical options" to reduce bias against surgery [PT]	We removed the headings to save space
	Remove this page entirely as patients will be losing interest by this point [OS]	Opposing positive feedback on this section
	Patients	
	Acknowledge that timeframes are averages so patients don't get disheartened when they don't reach a milestone on time	We included timeframe ranges to address this comment
QUESTIONS TO CONSIDER WHEN TALKING WITH A HEALTH PROFESSIONAL		
	Health professionals	
Adding and removing questions	Remove questions (e.g. "Do I know enough about my condition"; "Have I considered my individual circumstances") [OS]	Opposing positive feedback on these questions
	Health professionals	
	Could replace "Questions to consider when talking with your doctor" section with "Any further questions, ask your doctor" to save space [GP]	Opposing positive feedback on this section
Modify the formatting	Change the heading of this section so it applies to GPs [PT]	Opposing feedback to change the heading of this section so it applies to any health professional
	Patients	
	Remove this whole section to create space	Opposing positive feedback on this section
	Categorise questions based on which health professional should answer them	Too much overlap between health professionals who could answer each question
ARE THERE OTHER THINGS I CAN DO?*		
	Health professionals	
Modify information to help people choose non-surgical options first	Move this section to the first page and make it clear surgery is a last resort [PT/CP]	We thought it was important to present the options (and evidence) before patients reflect on questions they could ask a health professional
	Be specific about what exercises can be done [PT/CP]	Beyond the scope of this decision aid

Emphasise that there is often no need for early surgery and no harms in delaying surgery [OS/PT]

We suggested patients ask a health professional the following question: "Can I have surgery later? If so, how long should I wait before considering surgery?"

OVERALL FEEDBACK

	Health professionals	
Reduce amount of information	A 2-page decision aid is ideal [PT/CP/GP]	Opposing feedback that all information in the decision aid is important
	The decision aid includes too much information [GP/OS/PT]	
	Create a simplified version of the decision aid for patients [PT]	Positive feedback from patients that this decision aid is easy to understand
	Remove some sections (e.g. questions to ask a health professional, references, rotator cuff repair surgery) [PT/OS]	Opposing positive feedback on these sections
	Health professionals	
More detail needed	Include a section on diagnostic imaging (X-Ray, MRI, Ultrasound) and the importance of not missing a serious disease [GP]	Beyond the scope of this decision aid
	More detail is needed if the decision aid will be used without input from a health professional [PT]	Positive feedback from patients that this decision aid is easy to understand
	Patients	
	Last page lacks a solution if a patient has tried everything else	There is no evidence to address this complex issue
		Positive feedback that the decision aid covers all important information
	Health professionals	
Formatting or distribution suggestions	Create separate decision aids for each procedure [CP/OS/GP]	This would prevent patients using the decision aid before consulting with a surgeon as they would not know which surgery they are most likely to receive
	Create separate decision aids for surgical and non-surgical options [GP]	The evidence compares surgery to non-surgical options, so it is important these options are listed in the same decision aid
	Create a video summary of the decision aid [PT/CP]	This is a consideration for a future project

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Acknowledge that treatment decisions might be influenced by the health professional the decision aid is discussed with [PT/OS]	We felt that this information would not add value to this decision aid
--	--

Patients	
-----------------	--

Include page numbers	
-----------------------------	--

Create several decision aids (e.g. one for each surgery, one for patients and one for health professionals)	This would prevent patients using the decision aid before consulting with a surgeon as they would not know which surgery they are most likely to receive
---	--

Remove 'disclosure' section	Opposing positive feedback on the this section
-----------------------------	--

Emphasise the question asking section and de-emphasise others (e.g. harms, causes of shoulder pain, references)	Opposing positive feedback on these sections
---	--

Health professionals	
-----------------------------	--

Suspects bias or questions relevance of the decision aid	Thought the decision aid's underlying goal is to reduce the use of surgery and thought it should be more balanced [OS]	Opposing positive feedback suggesting the presentation of options was balanced
---	--	--

Believes evidence is changing and the decision aid may become irrelevant overtime [OS]	We plan to update the decision aid as new evidence emerges
--	--

CP: chiropractor; GP: general practitioner; PT: physiotherapist; OP: osteopath; OS: orthopaedic surgeon.
 *: this section was removed from the decision aid to save space so we could provide more detail about non-surgical options on the first page.

bmjopen-2021-054033, first published from <http://bmjopen.bmj.com/> on December 12, 2023 by guest. Protected by copyright.

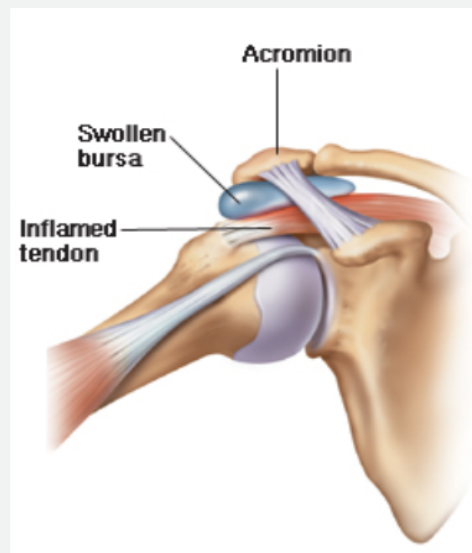
Shoulder pain: should I have arthroscopic surgery?

Is this decision aid relevant for me?

- This decision aid can help if you have shoulder pain due to common causes like rotator cuff tears or bursitis and are considering arthroscopic surgery of the shoulder

Cause and symptoms of shoulder pain

- **Shoulder pain** is commonly caused by rotator cuff tears, swelling of fluid filled sacs call bursa ('bursitis') or impingement.
- Impingement occurs due to contact between a bony part of the shoulder (the 'acromion') and the rotator cuff tendons or bursa (see picture). Contact usually occurs as you move your arm out to the side.
- Shoulder pain often makes it difficult to do simple everyday tasks like reaching into a high cupboard and washing hair.
- Symptoms often take time to settle and one half of patients are better by around 6 months.



SHOULDER PAIN:

SHOULD I HAVE SURGERY?

All information in this decision aid should be discussed with a health professional

+ Who should read this decision aid?

This decision aid is for people with persisting shoulder pain that is likely due to issues with rotator cuff tendons that move and support the shoulder (eg. inflammation, tears).

This type of pain often occurs around the shoulder. It makes it difficult to do simple tasks that involve lifting your arm above your head (eg. washing hair).

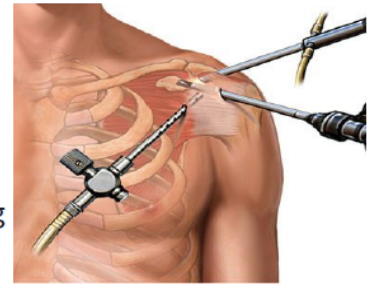
This decision aid does not apply to people who have other causes of shoulder pain like frozen shoulder (which causes pain and severe stiffness), osteoarthritis, or shoulder pain that begins after trauma immediately resulting in loss of movement or strength (eg. sudden rotator cuff tear, fracture, dislocation). If you're unsure of the cause of your pain, see a health professional.



What are the treatment options covered in this decision aid?

1. Surgery ('subacromial decompression' and/or 'rotator cuff repair')

Surgery requires admission to hospital and an anaesthetic. The surgeon will make a small skin cut in your shoulder to perform the procedure. Your surgeon may perform one or both of the following procedures:



- **Subacromial decompression:** Increase the space under the acromion by either shaving back some bone, trimming some ligament or removing a bursa
- **Rotator cuff repair:** Reconnecting torn rotator cuff tendons

The surgeon may only decide on which procedure to perform while in surgery.

2. No surgery

You can choose to not have surgery and instead have injections, physiotherapy, medication or wait to see if it improves by itself.

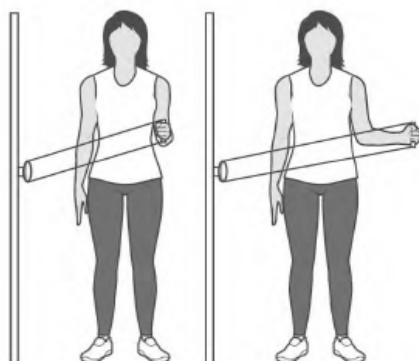


+ What are the treatment options covered in this decision aid?

NON-SURGICAL OPTIONS

Trying the following non-surgical options is recommended before considering surgery:

- Wait to see if your symptoms improve by themselves (roughly half of all people with these symptoms will recover within 6 months) and/or change your activities until the pain settles (eg. avoid carrying heavy grocery bags or take a break from sport if these activities cause pain)
- Take simple pain medicine (eg. paracetamol, anti-inflammatories)
- See a health professional (eg. physiotherapist) for advice on changing some daily activities and/or some muscle strength and endurance exercises
- See a health professional (eg. doctor) for a steroid injection



SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

You may consider surgery if the non-surgical options do not work and you can no longer put up with the pain. Typically surgery is not performed unless you have had symptoms for at least 3-6 months.

Surgery requires staying in hospital, having an anaesthetic and small skin cuts in your shoulder so the surgeon can perform one or both of the following:

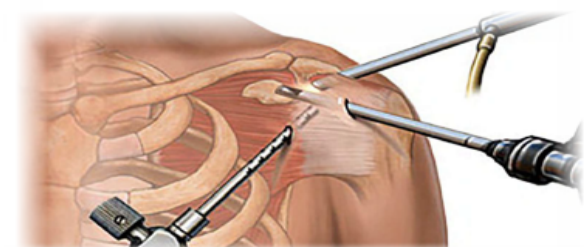
✓ Subacromial decompression surgery

Increase the space under the acromion by either shaving back some bone, trimming some ligament and/or removing a bursa

✓ Rotator cuff repair surgery

Reconnecting torn rotator cuff tendons

You will need to have rehabilitation involving exercises for at least 3 months following surgery. Much of this rehabilitation can be done at home.



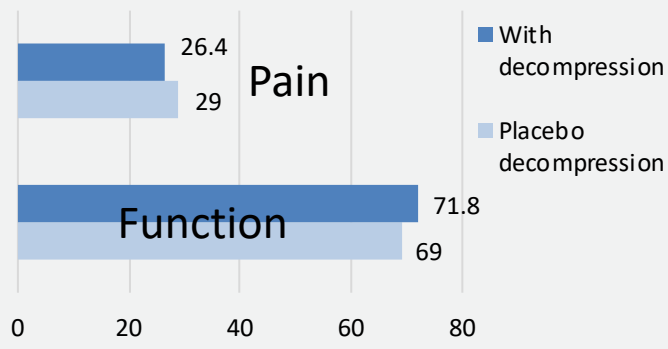
What are the likely benefits of arthroscopic surgery and non-surgical options?

Subacromial decompression vs. placebo

HIGH CERTAINTY EVIDENCE* that subacromial decompression is little-to-no better than placebo...

***We are very confident that the figures below represent the true benefits of surgery**

Placebo = the patient goes under anaesthetic and the surgeon inserts the surgical tools BUT no further procedure is performed



KEY MESSAGE: On average, surgery leads to **2.6% less pain** and **2.8% better function** compared to placebo surgery at 12 months.

Most patients would not consider these benefits important.

What % of people report treatment success?

- treatment success rated by patients
- treatment not a success

Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



71 out of 100 report success

Placebo



66 out of 100 report success

With surgery, **5 more people out of 100** will report their treatment as successful at 12 months.

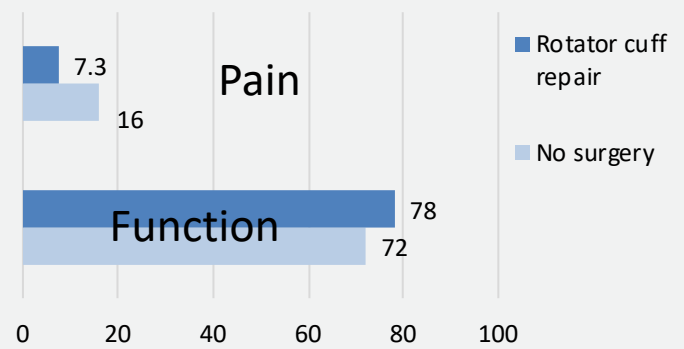
For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

Rotator cuff repair vs. no surgery

LOW-MODERATE CERTAINTY EVIDENCE* that rotator cuff repair is little-to-no better than no surgery...

***We have low-moderate confidence that the figures below represent the true benefits of surgery**

No surgery = injections, physiotherapy, medication or no treatment



KEY MESSAGE: On average, surgery leads to **8.7% less pain** and **6% better function** compared to no surgery at 12 months.

Most patients would not consider these benefits important.

What % of people report treatment success?

- treatment success rated by patients
- treatment not a success

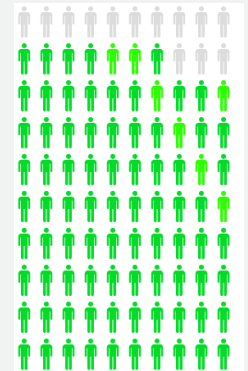
Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



95 out of 100 report success

No surgery



87 out of 100 report success

With surgery, **8 more people out of 100** will report their treatment as successful at 12 months.



+ What are the likely benefits of surgery compared to non-surgical options?

The figures on this page are based on the most up-to-date medical research as of 2020 (see references at the bottom of this page)

KEY MESSAGE

On average, patients report that surgery **improves pain and function by less than 10%** (ie. an improvement in pain or function of less than a 1 point on a 0-10 pain scale) compared to non-surgical options in the short term (6 months after) and longer term (1-2 years after) ^c. Because most patients do not notice these improvements, research concludes:

- Subacromial decompression surgery is not better than placebo or non-surgical options (ie. injections, exercise, medication or no treatment) for people with shoulder pain and no full-thickness rotator cuff tears ^a
- Rotator cuff repair surgery is little-to-no better than non-surgical options for people with full-thickness rotator cuff tears ^b

These results are averages. Surgery improves pain and function by more than 10% for some patients. But other patients have either **no improvements or worse** pain and function after surgery.

Further information:

^a For subacromial decompression surgery, we are very confident about this key message because research on this surgery is high-quality. This research was mostly conducted on people aged in their 40s, 50s and 60s, but is the best evidence we have for all ages.

^b For rotator cuff repair surgery, we are somewhat confident about this message because there is lack of high-quality research on this surgery. This research was mostly conducted on people aged in their 50s and 60s but is the best evidence we have for all ages. Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon.

^c Research suggests exercise or activities that you can do yourself at home may be just as helpful as a supervised exercise program.

Review only

What are the likely harms of arthroscopic surgery?

Each figure represents one person. We can't predict whether you will be one of the people who is harmed.



Based on moderate-certainty evidence, **less than 1 person per 100** that receives arthroscopic surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, deep vein thrombosis, pulmonary embolism, heart attack, stroke and pneumonia.

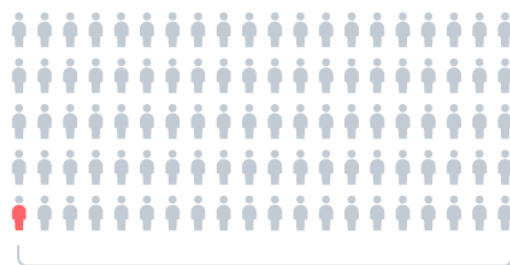


What are the likely harms of surgery?

Think of each figure as **1 person**. We can't predict if you will be one of the people who is harmed. Harms are more common among people with other health conditions (e.g. diabetes, heart disease).



About 3 people per 100 that have surgery will develop frozen shoulder (which may cause shoulder pain and stiffness for up to 2 years) or minor harms with surgery.

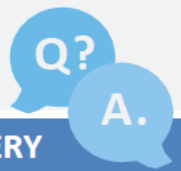


About 1 person per 100 that has surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, heart attack, stroke and pneumonia.

only

What practical issues should I consider?

The table shows key practical issues for those who have arthroscopic surgery and those who do not.



	ARTHROSCOPIC SURGERY	NO SURGERY
Procedure and follow-up	Performed by a surgeon in an operating theatre. Requires an anesthetic. Individualised follow-up with wound care and exercise	Advice from a professional about other treatments may be useful (eg. injections, exercise, activity modification, medication)
Recuperation	You may use a sling a few days after surgery. Recuperation typically takes between 2-6 weeks	No recuperation needed
Activity restrictions	Avoid heavy lifting for 7-21 days, overhead activities for 6 weeks and pushing through your hands for 3 months	No activity restrictions
Time off work	Depends on recovery and demands of job. Usually a few weeks after surgery	No time off work
Driving	You can start driving as soon as you feel able to steer. This is normally after one week	No driving limitations
Costs	Out-of-pocket costs for surgery are generally high. There may also be out-of-pocket costs for physiotherapy after surgery	No surgical costs BUT there may be out-of-pocket costs for physiotherapy or injections



+ Summary of benefits, harms, and other practical issues

NON-SURGICAL OPTIONS

✓ Potential benefits

- May **improve by itself** (within 6 months half of people will recover) or with non-surgical options (ie. injections, exercise, or medication)
- **Avoid surgery**

− Potential harms

- May decide to **have surgery later**
- **Cost of non-surgical options** (eg. injection, physiotherapy)
- **Time to attend health appointments** (eg. for physiotherapy)
- Regardless of what treatment you have, your symptoms **may not improve**

SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

✓ Potential benefits

- May provide **slight improvement in pain and function** compared to non-surgical options

− Potential harms

- Possible **surgical harms** (eg. frozen shoulder, infection)
- Your symptoms **may not improve** with surgery
- **Symptoms will temporarily be worse after surgery** due to the operation (eg. pain when sleeping or moving your arm)
- **Rehabilitation for 3-12 months** after surgery and time to attend rehabilitation
- May take up to **6 weeks** after subacromial decompression and **12 weeks** after rotator cuff repair to perform daily activities (eg. reach above your head, lift heavy objects)
- May take **3-4 months** after subacromial decompression and **6-12 months** after rotator cuff repair to return to heavy manual work, exercise, or sport
- **Out-of-pocket costs** are generally higher for surgery than non-surgical options. There may be **costs for rehabilitation** after surgery and due to **time needed off work**






Are there other things I can do?

- Strength and endurance exercises for your shoulder might help reduce pain and improve function.
- Modifying your activities and using pain relieving medicines when needed might help reduce pain.
- Seek advice from a health professional about the options that best suit your needs.
- Consider surgery at a later point if the above points do not help

Questions to consider when talking with your doctor...

- Do I need arthroscopic surgery?
- What happens if I don't have arthroscopic surgery?
- Do I know enough about the benefits and harms of:
 - » having arthroscopic surgery of the shoulder?
 - » not having arthroscopic surgery?
- Am I clear about which benefits and harms matter most to me?
- Do I have enough information and support to decide?

+ Questions to consider when talking with a health professional...

-  Do I need surgery? What happens if I don't have surgery? What happens if I do nothing?
-  Is surgery suitable for me? Which surgery is suitable for my diagnosis?
-  Can I have surgery later? If so, how long should I wait before considering surgery?
-  Have I considered my situation before making any decisions (eg. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport, etc)?
-  Do I understand enough about my condition and the benefits and harms of having surgery and not having surgery?



Supplementary File 1. Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Items	Guide questions/description	Yes/No
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Yes
Credentials	What were the researcher's credentials? e.g., PhD, MD	Yes
Occupation	What was their occupation at the time of the study?	Yes
Gender	Was the researcher male or female?	Yes
Experience and training	What experience or training did the researcher have?	Yes
Relationship established	Was a relationship established prior to study commencement?	Yes
Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	No
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic	Yes
Methodological orientation and theory	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Yes
Sampling	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Yes
Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Yes
Sample size	How many participants were in the study?	Yes
Non-participation	How many people refused to participate or dropped out? Reasons?	Yes
Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Yes
Presence of non-participants	Was anyone else present besides the participants and researchers?	Yes
Description of sample	What are the important characteristics of the sample? e.g., demographic data, date	Yes
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Yes
Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes
Field notes	Were field notes made during and/or after the interview or focus group?	Yes
Duration	What was the duration of the interviews or focus group?	Yes
Data saturation	Was data saturation discussed?	Yes

Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Yes
Number of data coders	How many data coders coded the data?	Yes
Description of the coding tree	Did authors provide a description of the coding tree?	Yes
Derivation of themes	Were themes identified in advance or derived from the data?	Yes
Software	What software, if applicable, was used to manage the data?	Yes
Participants checking	Did participants provide feedback on the findings?	Yes
Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Yes
Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
Clarity of major themes	Were major themes clearly presented in the findings?	Yes
Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

BMJ Open

Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery: an international mixed-methods study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-054032.R1
Article Type:	Original research
Date Submitted by the Author:	08-Aug-2021
Complete List of Authors:	Zadro, Joshua; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Jones, Caitlin; The University of Sydney Harris, Ian; UNSW Buchbinder, Rachele; Monash University, Dept of Epidemiology and Preventive Medicine O'Connor, Denise; Monash University, School of Public Health and Preventive Medicine McCaffery, Kirsten; The University of Sydney, Sydney Health Literacy Lab, School of Public Health Thompson, Rachel ; University of Sydney, School of Public Health Karunaratne, Sascha; Royal Prince Alfred Hospital, Surgical Outcomes Research Centre (SOuRCe) Teng, Min Jiat; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Maher, Christopher; University of Sydney, Institute for Musculoskeletal Health, School of Public Health Hoffmann, Tammy; Bond University
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PRIMARY CARE, REHABILITATION MEDICINE, Orthopaedic & trauma surgery < SURGERY

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **1 Development of a patient decision aid on subacromial decompression surgery and**
4
5 **2 rotator cuff repair surgery: an international mixed-methods study**
6
7

8 3 Joshua R Zadro^{a*}, Caitlin Jones^a, Ian A Harris^{a,b}, Rachele Buchbinder^{c,d}, Denise O'Connor^{c,d},
9
10 4 Kirsten McCaffery^e, Rachel Thompson^e, Sascha Karunaratne^f, Min Jiat Teng^a, Christopher
11
12 5 Maher^a, Tammy Hoffmann^g.
13
14

15
16 6 ^aInstitute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health,
17
18 7 The University of Sydney, New South Wales, Australia.
19

20
21 8 ^bIngham Institute for Applied Medical Research, South Western Sydney Clinical School,
22
23 9 UNSW Sydney, New South Wales, Australia.
24

25
26 10 ^cDepartment of Epidemiology and Preventive Medicine, School of Public Health and
27
28 11 Preventive Medicine, Monash University, Victoria, Australia.
29

30
31 12 ^dMonash Department of Clinical Epidemiology, Cabrini Institute, Victoria, Australia.
32

33
34 13 ^eSchool of Public Health, Faculty of Medicine and Health, The University of Sydney, New
35
36 14 South Wales, Australia.
37

38
39 15 ^fSurgical Outcomes Research Centre, Royal Prince Alfred Hospital, New South Wales,
40
41 16 Australia.
42

43
44 17 ^gInstitute for Evidence-Based Healthcare, Faculty of Health Sciences and Medicine, Bond
45
46 18 University, Queensland, Australia.
47

48
49 20 *Corresponding author: Dr Joshua R Zadro - Level 10 North, King George V Building, Royal
50
51 21 Prince Alfred Hospital, PO Box M179, Missenden Road, Camperdown, NSW, 2050,
52
53 22 Australia. Telephone: +61 2 8627 6782. Email: joshua.zadro@sydney.edu.au
54
55 23
56
57 24
58
59
60

1
2
3 25 **ABSTRACT**
4

5 26 **Objective:** To develop and user test a patient decision aid for people with subacromial pain
6
7
8 27 syndrome that presents evidence-based information on the benefits and harms of subacromial
9
10 28 decompression surgery and rotator cuff repair surgery.

11
12 29 **Design:** Mixed-methods study outlining the development of a patient decision aid.

13
14 30 **Setting:** We assembled a multidisciplinary steering group, and used existing decision aids and
15
16
17 31 decision science to draft the decision aid. Participants were recruited through social media (not
18
19 32 restricted by country nor setting), local hospitals, and the authors' collaboration network.

20
21 33 **Participants:** People with shoulder pain and health professionals who manage people with
22
23 34 shoulder pain.

24
25 35 **Primary and secondary outcomes:** We interviewed participants to gather feedback on the
26
27 36 decision aid, assessed useability and acceptability (using qualitative and quantitative methods),
28
29 37 and performed iterative cycles of re-drafting the decision aid and re-interviewing participants
30
31 38 as necessary. Interview data were analysed using thematic analysis. Quantitative data were
32
33 39 summarised descriptively.

34
35 40 **Results:** We interviewed 26 health professionals (11 physiotherapists, 7 orthopaedic surgeons,
36
37 41 4 general practitioners, 3 chiropractors and 1 osteopath) and 14 people with shoulder pain.
38
39 42 Most health professionals and people with shoulder pain rated all aspects of decision aid
40
41 43 acceptability as adequate-to-excellent (e.g., length, presentation, comprehensibility).
42
43 44 Interviews highlighted agreement among health professionals and people with shoulder pain
44
45 45 on most aspects of the decision aid (e.g. treatment options, summary of benefits, harms and
46
47 46 practical issues, questions to ask a health professional, graphics, formatting). However, some
48
49 47 aspects of the decision aid elicited divergent views among health professionals (e.g. causes and
50
51 48 symptoms of shoulder pain, evidence on benefits and harms).

52
53 49 **Conclusion:** This decision aid could be an acceptable and valuable tool for helping people with
54
55
56
57
58
59
60

1
2
3 50 subacromial pain syndrome make informed treatment choices. A randomised controlled trial
4
5 51 evaluating whether this decision aid reduces people's intentions to undergo shoulder surgery
6
7
8 52 and facilitates informed treatment choices is underway.
9

10 53 **Key words:** shoulder surgery; subacromial decompression; rotator cuff repair; decision aid;
11
12 54 shared decision making.
13
14

15 55
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

1
2
3 56 **Strengths and limitations of this study**
4
5

- 6 57 - This is the first study to rigorously describe the development of a patient decision aid
7
8 58 for people with subacromial pain syndrome that presents evidence-based information
9
10 59 on the benefits and harms of subacromial decompression surgery and rotator cuff repair
11
12 60 surgery, compared to non-surgical options
13
14
15 61 - We developed the patient decision aid with guidance from the International Patient
16
17 62 Decision Aids Standards, used a mixed methods approach to evaluate useability and
18
19 63 acceptability, interviewed a broad range of health professionals and patients, and
20
21 64 conducted one-on-one interviews which allowed in-depth feedback on the decision aid
22
23
24 65 - Our decision aid includes several key features recommended to optimise risk
25
26 66 communication (e.g. presenting numeric estimates, presenting uncertainty, using
27
28 67 visuals, tailoring estimates)
29
30
31 68 - Limitations include a small sample size for our quantitative acceptability data, being
32
33 69 unable to recruit certain groups of health professionals (e.g. rheumatologists, sports
34
35 70 doctors), and only interviewing people who speak English
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1. Introduction

Subacromial decompression surgery and rotator cuff repair surgery (with or without decompression) are frequently performed for people with subacromial pain syndrome[1-4] – an umbrella diagnosis that accounts for 85% of cases of shoulder pain (including rotator cuff tears) – but evidence suggests these procedures provide limited clinical benefit. Subacromial decompression surgery is not superior to placebo (high-certainty evidence) or non-surgical options, such as exercise and glucocorticoid injections (low- to moderate-certainty evidence), for improving pain and function in people with subacromial pain syndrome[5]. Rotator cuff repair surgery is not superior to non-surgical options for degenerative rotator cuff tears (low- to moderate-certainty evidence)[6]. Serious harms (e.g. infection) are experienced by 6/1000 people that have arthroscopic shoulder surgery[5].

Use of subacromial decompression surgery and rotator cuff repair surgery is increasing globally[1-4] despite the above evidence, suggesting people may not be making informed treatment choices. In Australia, the annual number of subacromial decompression surgeries performed increased from 3,536 to 7,455 between 2000 and 2019, while the number of rotator cuff repair surgeries performed increased from 6,212 to 12,436 during this period[1]. Increases have also been reported in the United States[4], England[2, 7] and Finland[3].

Patient decision aids present unbiased information on the benefits and harms of different healthcare options. A decision aid on options for treating subacromial pain syndrome could help patients make informed treatment choices and result in less use of unnecessary surgery. A Cochrane review of 105 studies (n=31,043) found that people exposed to decision aids made more informed choices about their healthcare and had a more active role in decision making, with no negative effects on outcomes or satisfaction[8]. For some conditions, patients were also more likely to choose less invasive treatment options[8].

1
2
3 95 By eliciting views of key stakeholders using mixed-methods, our aim was to develop a patient
4
5 96 decision aid for people with subacromial pain syndrome that presents evidence-based
6
7 97 information on the benefits and harms of subacromial decompression surgery and rotator cuff
8
9 98 repair surgery for subacromial pain syndrome (compared to non-surgical options).
10
11
12

13 99 **2. Methods**

14 15 100 **2.1. Initial decision aid design**

16
17
18 101 We developed a patient decision aid with guidance from the International Patient Decision Aids
19
20 102 Standards (IPDAS) using mixed-methods[9, 10]. We began by assembling a multidisciplinary
21
22 103 steering group (study authors) including topic experts (IH: orthopaedic surgery; RB: shoulder
23
24 104 pain; KM, TH, RT and DO: patient decision aids and shared decision making) and health
25
26 105 professionals who manage people with shoulder pain (JZ and SK: physiotherapists; RB:
27
28 106 rheumatologist). The first draft of the decision aid was created in PowerPoint and based on
29
30 107 decision aids for antibiotics[11] and knee arthroscopy[12] which several study authors have
31
32 108 developed (TH, KM, RB, DO and IH) (Supplementary File 1). Key features adapted from these
33
34 109 decision aids included horizontal bar graphs displaying the effects of surgery compared to
35
36 110 placebo and non-surgical options (which included injections, physiotherapy, medication and
37
38 111 wait and see), icon arrays to help patients understand probabilities, a statement about the source
39
40 112 and quality of the evidence, questions for patients to ask their health professional, and practical
41
42 113 issues (e.g. time off work, driving restrictions). Decision science evidence suggests these
43
44 114 features improve patient decision making[13-17]. Data from the 2019 Cochrane reviews on
45
46 115 subacromial decompression surgery[5] and rotator cuff repair surgery[6] were used to inform
47
48 116 numeric estimates of benefits and harms used in the decision aid. Expert opinion and consensus
49
50 117 from the steering group was used to inform all information presented in the decision aid (e.g.
51
52 118 causes and symptoms of shoulder pain, practical issues). The steering group provided feedback
53
54
55
56
57
58
59
60

1
2
3 119 on the first draft before we conducted semi-structured interviews with people with shoulder
4
5 120 pain and health professionals who manage people with shoulder pain.
6
7

8 121 **2.2. Participants**

9
10 122 Twenty-six health professionals involved in the management of shoulder pain were recruited
11
12 123 through social media, Royal Prince Alfred and Concord Hospitals in Sydney (Australia), and
13
14 124 the study authors' collaboration network. Health professionals had to manage/consult at least
15
16 125 five people with suspected subacromial pain syndrome per year. There was no restriction on
17
18 126 the type of health professional (e.g. orthopaedic surgeon, physiotherapist, general practitioner),
19
20 127 work setting or country of practice, or years of experience. Fourteen people with self-reported
21
22 128 shoulder pain (hereafter referred to as 'patients') were recruited through social media and
23
24 129 referrals from health professionals who participated in the study. Patients had to be ≥ 18 years
25
26 130 old and able to understand and communicate in English to participate. There was no restriction
27
28 131 on their country of birth. Enrolled participants were asked if they had any contacts who met
29
30 132 our inclusion criteria (snowballing). We purposively sampled participants to achieve diversity
31
32 133 in age, gender and ethnicity. For health professionals, we also purposively sampled to achieve
33
34 134 diversity in profession, years of experience and country of practice. All recruitment and data
35
36 135 collection procedures were approved by the Sydney Local Health District Human Research
37
38 136 Ethics Committee (Reference number: X20-0023). All participants provided consent by
39
40 137 checking a box before proceeding to the pre-interview online questionnaire that confirmed they
41
42 138 had read the Participants Information Sheet and Consent form and agree to participate in the
43
44 139 study.
45
46
47
48
49

50 140 **2.3. Data collection**

51
52 141 We reported the qualitative aspect of this study according to the 32-item Consolidated Criteria
53
54 142 for Reporting Qualitative Research (COREQ) checklist (Supplementary File 2)[18]. Box 1
55
56 143 describes the data collection process including the pre-interview questionnaires (used to
57
58
59
60

1
2
3 144 purposively sample participants; Supplementary Files 3 & 4), semi-structured interviews (topic
4
5 145 guides in Supplementary Files 5 & 6) and acceptability questionnaires (Supplementary Files 7
6
7
8 146 & 8). In accordance with IPDAS guidance[9, 10], semi-structured interviews were used to
9
10 147 assess patients' views on decisional needs and health professionals' views on patients'
11
12 148 decisional needs, gather feedback on the draft decision aid, and assess useability and
13
14 149 acceptability of the decision aid. Participants were provided the draft decision aid prior to the
15
16 150 interview but some participants did not review it beforehand. At the end of each interview,
17
18 151 participants were given the opportunity to provide any additional feedback or comments.
19
20 152 Changes to the decision aid were made throughout the interview process. Modifications were
21
22 153 compared to older versions of the decision aid to understand whether changes were useful.
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Box 1. Data collection process

Pre-interview questionnaires used to purposively sample participants

For health professionals, we gathered data on demographics, profession, years of experience, clinical setting, and number of patients with subacromial pain syndrome seen per year (Supplementary File 3). For patients, we gathered data on demographics (e.g., age, gender), duration and severity of shoulder pain, and previous treatments, previous imaging, and previous sick leave for shoulder pain (Supplementary File 4).

Semi-structured interviews

Interviews were used to gather feedback on the best way to present different aspects of the decision aid, such as treatment options, numeric estimates of benefits and harms, practical issues, and questions to ask a health professional. Participants were then asked to ‘think out loud’ while they read through the decision aid. They were encouraged to say everything that came to mind (e.g. concepts that might be challenging to understand, what their eye was drawn to) and give feedback on how the decision aid could be improved. The researcher conducting the interview used additional questions to prompt participants who were unsure of what to say. For example, some participants were prompted to give feedback on the relevance, usefulness, formatting, and language of each section, and the use of images. Interview guides for health professionals and patients are in Supplementary File 5 and Supplementary File 6 respectively.

Acceptability questionnaires

After the first round of interviews (n=12 health professionals; n=7 patients) and several re-drafts, we began assessing acceptability with a brief questionnaire at the end of each interview because we felt we were getting close to the final version of the decision aid. A separate questionnaire, adapted from The Ottawa Hospital Research Institute[19], was used for health professionals (Supplementary File 7) and patients (Supplementary File 8).

1
2
3 155 All interviews were conducted one-on-one via videoconference due to COVID-19. All
4
5 156 interviews lasted between 30-60 minutes and were conducted by a researcher with experience
6
7 157 in conducting qualitative interviews (CJ). The interviewer was a female PhD candidate and
8
9 158 occupational therapist. Two pilot interviews were conducted before recruitment to test the
10
11 159 interview guides. During participant interviews, the interviewer took notes to highlight key
12
13 160 concepts emerging from the interview and direct further questioning. The interviewer did not
14
15 161 have an established relationship with participants prior to the study commencing. Participants
16
17 162 were informed of the reason for the study prior to being interviewed. All interviews were audio-
18
19 163 recorded (with verbal consent obtained from participants) and transcribed verbatim for
20
21 164 analysis. All participants had the opportunity to review the transcript of their interview prior to
22
23 165 data analysis if they wished. Health professionals and patients and who completed an interview
24
25 166 were compensated for their time with a \$100 and \$50 supermarket gift card, respectively.
26
27 167 Health professionals were compensated with more money to account for potentially sacrificing
28
29 168 appointment slots to participate in this study.
30
31
32
33
34
35

36 169 **2.4. Data analysis**

37
38 170 Pre-interview and acceptability questionnaire responses were summarised using descriptive
39
40 171 statistics (means and standard deviations [SD], counts and percentages). For the health
41
42 172 professional acceptability questionnaire (Supplementary File 7), a 5-point Likert scale
43
44 173 (strongly agree = 5; strongly disagree = 1) was used to assess agreement with various
45
46 174 statements. We presented Likert scores as the percentage of responses for each category and as
47
48 175 means (SD). We also calculated mean (SD) agreement scores for orthopaedic surgeons
49
50 176 separately as we anticipated they might have different views on a decision aid for people
51
52 177 considering surgery compared to other health professionals. For the patient acceptability
53
54 178 questionnaire (Supplementary File 8), impressions of different sections of the decision aid were
55
56 179 dichotomised as 'excellent/good' vs. 'fair/poor'.
57
58
59
60

1
2
3 180 All interview data were analysed using thematic analysis; a method for identifying, analysing
4
5 181 and reporting patterns within data[20]. Grounded theory using an inductive approach
6
7 182 underpinned how data was collected and analysed. Two researchers (CJ and JZ) independently
8
9 183 familiarised themselves with the interviews (via audio-recordings or transcripts), recorded
10
11 184 initial observations, and identified concepts relevant to the questions asked. The two
12
13 185 researchers developed a framework to organise concepts into broader themes and sub-themes
14
15 186 in Excel[21]. Any disagreements in categorising concepts into themes and sub-themes were
16
17 187 discussed and resolved. The mapping of themes and sub-themes was iterative as new data
18
19 188 emerged so that the decision aid was continually updated before new interviews were
20
21 189 conducted. Over 10 iterative cycles of revisions were performed. However, in some cases these
22
23 190 were very minor changes (e.g. correcting typos, re-wording a sentence). Patients' views on
24
25 191 decisional needs and health professionals' views on patients' decisional needs were integrated
26
27 192 with the feedback given on each section of the decision aid to streamline the presentation of
28
29 193 the results. Interviews stopped once no new feedback was being provided (data saturation) and
30
31 194 participants had an overall positive impression of the decision aid.
32
33
34
35
36
37

38 195 **2.5. Patient or Public Involvement**

39
40 196 Patients and members of the public were not involved in the design of this study.
41
42

43 197 **3. Results**

44 198 **3.1. Adherence to the IPDAS criteria and user-centredness**

45
46 199 We determined that the decision aid (Supplementary File 9) met 6 out of 6 criteria to be
47
48 200 considered a decision aid, 6 out of 6 criteria to reduce the risk of harmful bias, and 20 and 23
49
50 201 quality criteria according to the IPDASi checklist (v4.0)[22] (Supplementary File 10). Our
51
52 202 decision aid also met 10 out of 11 criteria for user-centredness (Supplementary File 11), as
53
54 203 assessed by the User-Centered Design 11-item measure (UCD-11)[23].
55
56
57
58
59

60 204 **3.2. Participant characteristics and decision aid acceptability**

1
2
3 205 We interviewed 26 health professionals [11 (42%) physiotherapists, 7 (27%) orthopaedic
4
5 206 surgeons, 4 (15%) general practitioners, 3 (12%) chiropractors and 1 (4%) osteopath] and 14
6
7
8 207 patients. Repeat interviews were conducted with one of these health professionals
9
10 208 (physiotherapist) and four of these patients to explore whether initial feedback had been
11
12 209 addressed through modifications to the decision aid. No participant who completed the pre-
13
14 210 interview questionnaire refused an interview. However, a number of participants who
15
16 211 completed the pre-interview questionnaire were not interviewed since participants were
17
18 212 purposively sampled (n=130 health professional and n=19 patient respondents were not
19
20 213 interviewed). Health professional and patient characteristics are in Table 1. There were 15
21
22 214 health professionals and 11 patients that completed the acceptability questionnaire. All aspects
23
24 215 of decision aid acceptability were rated as adequate-to-excellent (e.g. length, amount of
25
26 216 information, presentation, comprehensibility) by most health professionals (Table 2) and
27
28 217 patients (Table 3). Figure 1 provides a summary of the development process.

218 **3.3. Feedback on each section of the decision aid**

219 Positive feedback for each section, and for the decision aid overall, largely included agreement
220 with the content, graphics, formatting, amount of information, and presentation of information.
221 Supplementary File 12 provides a summary of themes and sub-themes across sections of the
222 decision aid. Suggestions for improvement (themes) and examples (sub-themes) are
223 summarised below. Although most suggestions were implemented, some conflicted with others
224 or were not possible to implement. Supplementary File 13 outlines feedback we did not
225 incorporate in the decision aid and our justification for this. Feedback from three or more types
226 of health professionals was classified as 'multidisciplinary feedback'.

227 **3.3.1. Who should read this decision aid?**

1
2
3 228 This section covers the title of the decision aid, information about who should read the decision
4
5 229 aid, and common causes and symptoms of shoulder pain. Suggestions for improvement
6
7
8 230 (themes) with examples (sub-themes) included:

- 9
10 231 • Improve clarity on the target population (e.g. some GPs wanted this section to be more
11
12 232 concise, some patients thought softening the exclusion criteria would prevent people
13
14 233 with overlapping symptoms disregarding the decision aid)
15
16
17 234 • Highlight that patients need to discuss this decision aid with a health professional
18
19 235 (multidisciplinary feedback)
20
21
22 236 • Revise the causes and symptoms of shoulder pain (e.g. multidisciplinary feedback
23
24 237 suggested this information had a pathoanatomical focus that was inaccurate and that
25
26 238 this information could drive patients towards surgery)
27
28
29 239 • Use positive messaging (e.g. some physiotherapists thought the language would cause
30
31 240 fear among patients)
32
33
34 241 • Make this section more concise and relevant (e.g. multidisciplinary feedback suggested
35
36 242 the explanation of shoulder symptoms might be irrelevant for patients, some
37
38 243 orthopaedic surgeons wanted to emphasise the importance of a proper diagnosis to
39
40 244 guide treatment decisions)

41
42 245 Supplementary File 14 highlights changes between the first and final draft of this section.
43
44
45
46 246

47 48 247 **3.3.2. What are the treatment options covered in this decision aid?**

49
50
51 248 This section outlines non-surgical and surgical management options for subacromial pain
52
53 249 syndrome. Suggestions for improvement included:

- 54
55 250 • Include more detail on non-surgical options and how to progress management (e.g.
56
57 251 multidisciplinary feedback suggested balancing the amount of information between the
58
59
60

- 1
2
3 252 non-surgical and surgical options, some patients wanted more information on ‘wait and
4
5 253 see’ and how to modify activities)
6
7
8 254 • Change the non-surgical options presented (e.g. some physiotherapists thought it was
9
10 255 inappropriate to include medication and injections as options, some physiotherapists
11
12 256 and chiropractors thought the order of non-surgical options might be inappropriate)
13
14
15 257 • Include indications for surgery (e.g. multidisciplinary feedback suggested the inclusion
16
17 258 of indicators for each surgery like failed conservative management, severe pain, age
18
19 259 and massive cuff tears)
20
21
22 260 • Present evidence of benefits and harms in this section (e.g. multidisciplinary feedback
23
24 261 suggested mentioning the success rate of surgery and non-surgical options, and
25
26 262 emphasise the harms of surgery)
27
28
29 263 • Change the information on surgery (e.g. some patients wanted more detail on surgery
30
31 264 and rehabilitation, while others wanted less detail on the procedures)
32
33
34 265 • Modify the formatting and graphics (e.g. multidisciplinary feedback suggested listing
35
36 266 non-surgical options first, some patients wanted more space between the options and
37
38 267 thought the image of surgery was too graphic).

39
40 268 Supplementary File 15 highlights changes between the first and final draft of this section.
41
42

43 269 **3.3.3. What are the likely benefits of surgery compared to non-surgical options?**

44
45 270 This section summarises data on the effectiveness of subacromial decompression surgery and
46
47
48 271 rotator cuff repair surgery compared to non-surgical options from two Cochrane reviews [5, 6].
49

50 272 Suggestions for improvement included:

- 51
52 273 • Revise the description for the certainty of evidence (e.g. some physiotherapists and
53
54 274 chiropractors thought using a green font for high-certainty evidence would drive
55
56
57 275 patients towards surgery)
58
59
60

- 1
2
3 276 • Evidence doesn't match experience, more clarification needed (e.g. some orthopaedic
4
5 277 surgeons thought the evidence from Cochrane reviews may not be generalizable,
6
7 278 surgery may improve the speed of recovery and surgery may be useful for preventing
8
9 279 tears progressing even if there was no improvement in symptoms, some orthopaedic
10
11 280 surgeons and GPs thought it was important to acknowledge evidence represents
12
13 281 averages and careful selection of surgical candidates could yield positive results)
14
15 282 • Simplify the statistics (e.g. some physiotherapists and chiropractors thought 'key
16
17 283 messages' could be used instead of a bar graph, some orthopaedic surgeons thought
18
19 284 repetition of statistics was unnecessary and biased against surgery)
20
21 285 • Provide more detail or revise the description of the evidence (e.g. some patients wanted
22
23 286 information on the source of the evidence and more explanation about the certainty of
24
25 287 evidence)
26
27 288 • Contextualise the evidence to reflect uncertainty on an individual level (e.g. some
28
29 289 patients wanted to highlight the numeric estimates were averages)
30
31 290 • Modify the formatting and language used (e.g. some GPs and patients wanted to
32
33 291 shorten the key messages box and include other information as footnotes, some patients
34
35 292 thought the icon array wasn't useful).

36
37
38
39
40
41
42 293 Supplementary File 16 highlights changes between the first and final draft of this section.

43 44 45 294 **3.3.4. What are the likely harms of surgery?**

46
47 295 This section summarises data on the potential harms of subacromial decompression and rotator
48
49 296 cuff repair surgery from two Cochrane reviews[5, 6]. Data on the potential harms of non-
50
51 297 surgical options was not available. Suggestions for improvement included:

- 52
53 298 • Present both minor and serious harms (multidisciplinary feedback)
54
55 299 • Provide more context for harms (e.g. some physiotherapists and chiropractors
56
57 300 suggested comparing the harms of surgery and non-surgical options, some GPs and
58
59
60

- 1
2
3 301 patients thought presenting harms in a different section to ‘benefits’ doesn’t give an
4
5 302 understanding of harm versus benefit)
6
7
8 303 • Clarify the evidence as it does not match personal experience (e.g. some orthopaedic
9
10 304 surgeons thought harms were overestimated, some physiotherapists thought harms
11
12 305 were underestimated)
13
14
15 306 • Modify the formatting and language used (e.g. some orthopaedic surgeons and patients
16
17 307 thought ‘harm’ was too negative and suggested replacing it with ‘risk’).

18
19 308 Supplementary File 17 highlights changes between the first and final draft of this section.
20
21

22 309 **3.3.5. Summary of benefits, harms, and other practical issues**

23
24 310 This section provides a summary of the benefits, harms, and important practical issues of
25
26 311 surgery and non-surgical options. Suggestions for improvement included:
27
28

- 29 312 • Revise information on costs (e.g. some physiotherapists and GPs wanted specific cost
30
31 313 information on surgery, some orthopaedic surgeons wanted to soften the language
32
33 314 emphasising the costs of surgery, some chiropractors and patients wanted information
34
35 315 on the costs of non-surgical options)
36
37
38 316 • Revise information on activity restrictions and post-surgical management (e.g. some
39
40 317 physiotherapists and orthopaedic surgeons suggested alternative timeframes for post-
41
42 318 surgery activity restrictions, some GPs wanted to emphasise symptoms may improve
43
44 319 with or without surgery)
45
46
47 320 • Modify the formatting or language used (e.g. some GPs and patients wanted to separate
48
49 321 the practical issues by type of surgery, while some physiotherapists thought this would
50
51 322 result in too much information).
52
53

54 323 Supplementary File 18 highlights changes between the first and final draft of this section.
55
56

57 324 **3.3.6. Questions to consider when talking with a health professional**

1
2
3 325 This section outlines questions patients should consider asking their health professional before
4
5 326 deciding to have surgery. Suggestions for improvement included:

- 7
8 327 • Adding questions (e.g. some physiotherapists suggested “How long should I wait
9
10 328 before considering surgery?”)
- 12 329 • Removing questions (e.g. some orthopaedic surgeons suggested removing “Do I know
13
14 330 enough about my condition” and “Have I considered my individual circumstances?”)
- 16 331 • Modifying the formatting (e.g. some physiotherapists wanted the heading to be
17
18 332 inclusive of any health professional while others thought these questions were better
19
20 333 suited to GPs).

23
24 334 An early version of the decision aid included a section on ‘Are there other things I can do?
25
26 335 Suggestions included activity modification, strength, and endurance exercises, seeking advice
27
28 336 from a health professional, and considering surgery if these options don’t help. We received
29
30 337 positive feedback from patients on this section and helpful suggestions from health
31
32 338 professionals to add information to help people try non-surgical options first. However, we
33
34 339 decided to remove this section to save space so we could provide more detail about non-surgical
35
36 340 options on the first page.

37
38
39 341 Supplementary File 19 highlights changes between the first and final draft of this section.

42 43 342 **3.3.7. Overall feedback**

44
45 343 Overall feedback included:

- 46
47
48 344 • Reduce the amount of information (e.g. multidisciplinary feedback suggested a 2-page
49
50 345 decision aid was ideal, some physiotherapists and orthopaedic surgeons suggested
51
52 346 removing the question-asking section and the references)
- 54 347 • More detail needed (e.g. some GPs wanted information on imaging and the importance
55
56 348 of not missing a serious disease, some patients thought the last page lacked a solution
57
58 349 if someone had tried everything)
- 59
60

1
2
3 350 • Formatting and distribution suggestions (e.g. multidisciplinary feedback and feedback
4
5 351 from patients suggested separate decision aids for each surgery was needed, some GPs
6
7
8 352 wanted separate decision aids for surgical and non-surgical options, some
9
10 353 physiotherapists and chiropractors suggested making a video summary of the decision
11
12 354 aid, some physiotherapists and orthopaedic surgeons suggested the decision aid should
13
14
15 355 be provided in clinics, early during treatment, when patients are considering surgery
16
17 356 and/or after a patient received a diagnosis, some patients suggested emphasising the
18
19 357 question-asking section).

21 358 Some orthopaedic surgeons felt the decision aid was not balanced and biased against surgery.
22
23 359 Most patients stated that the decision aid had swayed them away from surgery. One patient was
24
25 360 initially sway towards surgery after reading the decision aid – to have surgery before the risk
26
27 361 of complications increased or pain got worse – but changed their mind after reviewing the
28
29 362 decision aid in a repeat interview due to lack of evidence of benefit.
30
31
32

33 363 **4. Discussion**

34 364 **4.1. Summary of findings**

35
36 365 Most health professionals and people with shoulder pain rated all aspects of decision aid
37
38 366 acceptability as adequate-to-excellent (e.g., length, amount of information, presentation,
39
40 367 comprehensibility). Interviews highlighted agreement with most aspects of the decision aid
41
42 368 (e.g. treatment options, summary of benefits, harms and practical issues, questions to ask a
43
44 369 health professional, graphics, formatting, amount of information, and presentation of
45
46 370 information) and some divergent views among health professionals on parts of the decision aid
47
48 371 (e.g. causes and symptoms of shoulder pain, evidence on benefits and harms). To understand
49
50 372 whether this tool adds value to clinical practice, a randomised controlled trial evaluating
51
52 373 whether this decision aid reduces people's intentions to undergo shoulder surgery and
53
54 374 facilitates informed treatment choices is underway.
55
56
57
58
59
60

375 **4.2. Strengths and limitations of this study**

376 We developed a decision aid according to the IPDAS criteria, used a mixed methods approach
377 to evaluate useability and acceptability, interviewed a broad range of health professionals and
378 patients, and conducted one-on-one interviews which allowed in-depth feedback on the
379 decision aid. Our decision aid includes several key features recommended to optimise risk
380 communication (e.g. presenting numeric estimates, presenting uncertainty, using visuals,
381 tailoring estimates)[17]. Limitations include a small sample size for our quantitative
382 acceptability data, being unable to recruit certain groups of health professionals (e.g.
383 rheumatologists, sports doctors), and the decision aid only being developed in English (the
384 Steering group will consider cross-cultural adaptation of this tool following its evaluation in a
385 clinical trial). We also acknowledge that individual circumstances may limit the applicability
386 of the evidence presented in the decision aid (e.g. age, pain severity, activity levels, job
387 demands, insurance coverage, caring responsibilities, involvement in sport).

388 **4.3. Meaning of the study**

389 Interviews highlighted high levels of agreement with most aspects of the decision aid among
390 health professionals and patients, although we did find some divergent views among health
391 professionals on parts of the decision aid. Highly consistent feedback included praise for
392 including practical issues for surgery and non-surgical options and a global summary of the
393 benefits and harms of each, praise for including questions to ask a health professional, and a
394 comment that a 2-page decision aid would be ideal if it included all information from the 3-
395 page version. We attempted to create a 2-page version of the decision aid but were not able to
396 do so without comprising useability and acceptability or removing important information.

397 Health professionals and patients largely agreed with the presentation of non-surgical and
398 surgical options, with some patients pleased to have 'wait and see' included as this aligned
399 with their experience of pain that has resolved without treatment. Most health professionals

1
2
3 400 and patients wanted non-surgical options listed before surgery to mimic treatment
4
5 401 recommendations in real-life. However, evidence suggests people are more likely to think a
6
7 402 decision aid is balanced if options are listed side-by-side[13]. We listed the options side-by-
8
9 403 side, with non-surgical options on the left ('first'), as a compromise.

10
11
12
13 404 A few physiotherapists thought it was inappropriate to include medication and injections as
14
15 405 options and wanted physiotherapy-delivered treatments listed earlier. Cochrane reviews on
16
17 406 treatments for subacromial pain syndrome show glucocorticoid injections are superior to
18
19 407 placebo and provide similar effects to non-steroidal anti-inflammatory drugs[24] and
20
21 408 physiotherapy-delivered treatments (e.g. exercise, manual therapy, electrotherapy)[25, 26].
22
23 409 There is no evidence physiotherapy-delivered treatments are superior to placebo[25, 26]. For
24
25 410 these reasons, we did not action their suggestions.

26
27
28
29
30 411 We found quite varied feedback on the causes and symptoms of shoulder pain and presentation
31
32 412 of benefits. Most health professionals and patients thought the causes and symptoms of
33
34 413 shoulder pain were accurate and easy to understand. However, some health professionals
35
36 414 (mostly physiotherapists) thought the pathoanatomical description of shoulder pain was
37
38 415 inappropriate and used language that could cause fear and drive patients towards surgery. Some
39
40 416 health professionals and patients thought the icon array and bar graphs were helpful, which is
41
42 417 consistent with evidence suggesting these graphics help people make value-aligned
43
44 418 decisions[14]. However, we replaced some icon arrays and bar graphs with a 'key messages'
45
46 419 box to address feedback that the statistics needed to be simplified and less repetitive, and
47
48 420 because 'fact boxes' are useful risk-communicating tools[27]. We kept numeric estimates in the
49
50 421 key messages box due to evidence suggesting patients prefer numeric estimates over narrative
51
52 422 descriptions of effect sizes (e.g. 'small' effects)[28].
53
54
55
56
57
58
59
60

1
2
3 423 Some orthopaedic surgeons disagreed with evidence from Cochrane systematic reviews and
4
5 424 thought the decision aid was biased against surgery. Some believed that, if surgeons selected
6
7 425 surgical candidates carefully, surgery could improve the speed of recovery and prevent tears
8
9 426 progressing (outcomes not assessed in Cochrane reviews), while minimising the risk of harm.
10
11 427 On the other extreme were some physiotherapists, who suggested that Cochrane systematic
12
13 428 reviews have underestimated the true harms of surgery. We did not change the evidence
14
15 429 presented because it is vital numeric estimates of benefits and harms in decision aids are based
16
17 430 on the highest quality available evidence[15, 29].
18
19
20
21

22 431 Nearly 3 in 4 patients thought the decision aid was biased against surgery (Table 3), likely
23
24 432 because the evidence we presented shows subacromial decompression surgery and rotator cuff
25
26 433 repair surgery are not superior to non-surgical management[5, 6]. This suggests tools for
27
28 434 assessing perceived balance of decision aids may not be suitable when a decision aid presents
29
30 435 information that counters prevailing norms.
31
32
33

34 436 We included health professionals practising in various countries to maximise the acceptability
35
36 437 of this tool globally. As such, some information had to be made more general to accommodate
37
38 438 the characteristics of different health systems. For example, we could not be specific about the
39
40 439 costs of surgery or non-surgical options as this varies between countries due to factors like
41
42 440 health system and insurance coverage. We also received feedback to mention physiotherapists
43
44 441 as providers of injections as this is within the scope of some advanced practice physiotherapists
45
46 442 in the UK.
47
48
49

51 443 **4.4. Implications for future research**

52
53 444 We are currently evaluating a print/online version of the decision aid in a randomised
54
55 445 controlled trial including people with shoulder pain considering shoulder surgery. However,
56
57 446 feedback from health professionals raised the possibility of future trials evaluating different
58
59
60

1
2
3 447 formats of the decision aid (e.g. video summary, decision aid specific to one shoulder surgery)
4
5 448 in different populations (e.g. patients who have consulted with a surgeon and know what
6
7
8 449 surgery they are likely to receive).
9

10 11 450 **5. Conclusion**

12
13 451 By eliciting views of key stakeholders, we developed a patient decision aid that presents
14
15 452 evidence-based information on the benefits and harms of subacromial decompression surgery,
16
17 453 rotator cuff repair surgery and non-operative treatments for subacromial pain syndrome.
18
19 454 Acceptability testing and interviews with health professionals and people with shoulder pain
20
21 455 highlights this decision aid could be an acceptable and valuable tool for helping people with
22
23 456 shoulder pain make informed treatment choices. A randomised controlled trial evaluating
24
25 457 whether this decision aid reduces people's intentions to undergo shoulder surgery and
26
27 458 facilitates informed treatment choices is underway.
28
29
30

31
32 459
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 **460 Authors' contributions**
4

5 461 All authors critically revised the manuscript for important intellectual content and approved
6
7 462 the final manuscript. Please find below a detailed description of the role of each author:
8
9

- 10 463 - Joshua R Zadro: conception and design, analysis and interpretation of data, drafting and
11
12 464 revision of the manuscript, and final approval of the version to be published
13
14 465 - Caitlin Jones: conception and design, analysis and interpretation of data, drafting and
15
16 466 revision of the manuscript, and final approval of the version to be published
17
18 467 - Ian A Harris: conception and design, interpretation of data, drafting and revision of the
19
20 468 manuscript and final approval of the version to be published
21
22 469 - Rachelle Buchbinder: conception and design, interpretation of data, drafting and
23
24 470 revision of the manuscript and final approval of the version to be published
25
26 471 - Denise O'Connor: conception and design, interpretation of data, drafting and revision
27
28 472 of the manuscript and final approval of the version to be published
29
30 473 - Kirsten McCaffery: conception and design, interpretation of data, drafting and revision
31
32 474 of the manuscript and final approval of the version to be published
33
34 475 - Rachel Thompson: conception and design, interpretation of data, drafting and revision
35
36 476 of the manuscript and final approval of the version to be published
37
38 477 - Sascha Karunaratne: conception and design, interpretation of data, drafting and revision
39
40 478 of the manuscript and final approval of the version to be published
41
42 479 - Min Jiat Teng: conception and design, interpretation of data, drafting and revision of
43
44 480 the manuscript and final approval of the version to be published
45
46 481 - Christopher G Maher: conception and design, interpretation of data, drafting and
47
48 482 revision of the manuscript and final approval of the version to be published
49
50 483 - Tammy Hoffmann: conception and design, interpretation of data, drafting and revision
51
52 484 of the manuscript and final approval of the version to be published
53
54
55
56
57
58
59
60

1
2
3 485 The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that
4
5 486 no others meeting the criteria have been omitted.
6

7
8 487 **Competing interests:** All authors declare: no support from any organisation for the submitted
9
10 488 work; no financial relationships with any organisations that might have an interest in the
11
12 489 submitted work; no other relationships or activities that could appear to have influenced the
13
14 490 submitted work.
15

16
17 491 **Funding source:** This study was funded by the Arthritis Australia Grants-in-Aid scheme
18
19 492 (funder number N/A). The contribution of RT to this work was supported by a National Health
20
21 493 and Medical Research Council (NHMRC) Program Grant (APP1113532).
22

23
24 494 **Data availability statement:** All data relevant to the study are available upon reasonable
25
26 495 request to the corresponding author.
27

28
29 496 **Ethics statement:** All recruitment and data collection procedures were approved by the
30
31 497 Sydney Local Health District Human Research Ethics Committee (Reference number: X20-
32
33 498 0023).
34

35
36 499
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

1. Medicare Item Reports 2000/2001 to 2018/19. http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp. Accessed 1st June, 2020.
2. Judge A, Murphy RJ, Maxwell R, Arden NK, Carr AJ. Temporal trends and geographical variation in the use of subacromial decompression and rotator cuff repair of the shoulder in England. *Bone Joint J.* 2014;96-b(1):70-4.
3. Paloneva J, Lepola V, Äärimaa V, Joukainen A, Ylinen J, Mattila VM. Increasing incidence of rotator cuff repairs—A nationwide registry study in Finland. *BMC Musculoskelet Disord.* 2015;16(1):189.
4. Zhang AL, Montgomery SR, Ngo SS, Hame SL, Wang JC, Gamradt SC. Analysis of rotator cuff repair trends in a large private insurance population. *Arthroscopy.* 2013;29(4):623-9.
5. Karjalainen TV, Jain NB, Page CM, Lähdeoja TA, Johnston RV, Salamh P, et al. Subacromial decompression surgery for rotator cuff disease. *Cochrane Database Syst Rev.* 2019(1):CD005619.
6. Karjalainen TV, Jain NB, Heikkinen J, Johnston RV, Page CM, Buchbinder R. Surgery for rotator cuff tears. *Cochrane Database Syst Rev.* 2019(12):CD013502.
7. Jones T, Carr AJ, Beard D, Linton M-J, Rooshenas L, Donovan J, et al. Longitudinal study of use and cost of subacromial decompression surgery: the need for effective evaluation of surgical procedures to prevent overtreatment and wasted resources. *BMJ Open.* 2019;9(8):e030229-e.
8. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2017(4):CD001431.

- 1
2
3 525 9. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A
4
5 526 systematic development process for patient decision aids. *BMC Med Inform Decis Mak.*
6
7 527 2013;13 Suppl 2(Suppl 2):S2-S.
8
9
10 528 10. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a
11
12 529 quality criteria framework for patient decision aids: online international Delphi consensus
13
14 530 process. *BMJ.* 2006;333(7565):417.
15
16
17 531 11. Coxeter PD, Mar CD, Hoffmann TC. Parents' Expectations and Experiences of
18
19 532 Antibiotics for Acute Respiratory Infections in Primary Care. *Ann Fam Med.* 2017;15(2):149-
20
21 533 54.
22
23
24 534 12. O'Connor D, Hoffmann T, McCaffery K, Maher C, Harris I, Glasziou P, et al. 85
25
26 535 Evaluating a patient decision aid for people with degenerative knee disease considering
27
28 536 arthroscopic surgery: Protocol for a randomised controlled trial. *BMJ Evid Based Med.*
29
30 537 2019;24(Suppl 2):A48-A.
31
32
33 538 13. Abhyankar P, Volk RJ, Blumenthal-Barby J, Bravo P, Buchholz A, Ozanne E, et al.
34
35 539 Balancing the presentation of information and options in patient decision aids: an updated
36
37 540 review. *BMC Med Inform Decis Mak.* 2013;13 Suppl 2(Suppl 2):S6-S.
38
39
40 541 14. Carling CLL, Kristoffersen DT, Flottorp S, Fretheim A, Oxman AD, Schünemann HJ,
41
42 542 et al. The effect of alternative graphical displays used to present the benefits of antibiotics for
43
44 543 sore throat on decisions about whether to seek treatment: a randomized trial. *PLoS Med.*
45
46 544 2009;6(8):e1000140-e.
47
48
49 545 15. Montori VM, LeBlanc A, Buchholz A, Stilwell DL, Tsapas A. Basing information on
50
51 546 comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a
52
53 547 quality dimension of the International Patient Decision Aid Standards. *BMC Med Inform Decis*
54
55 548 *Mak.* 2013;13 Suppl 2(Suppl 2):S5-S.
56
57
58
59
60

- 1
2
3 549 16. Santesso N, Rader T, Nilsen ES, Glenton C, Rosenbaum S, Ciapponi A, et al. A
4
5 550 summary to communicate evidence from systematic reviews to the public improved
6
7 551 understanding and accessibility of information: a randomized controlled trial. *J Clin Epidemiol*.
8
9 552 2015;68(2):182-90.
- 10
11
12 553 17. Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PK, et al.
13
14 554 Presenting quantitative information about decision outcomes: a risk communication primer for
15
16 555 patient decision aid developers. *BMC Med Inform Decis Mak*. 2013;13 Suppl 2(Suppl 2):S7.
- 17
18
19 556 18. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research
20
21 557 (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*.
22
23 558 2007;19(6):349-57.
- 24
25
26 559 19. O'Connor AM, Cranney A. User Manual - Acceptability. 1996 [Updated 2002].
27
28 560 Available from www.ohri.ca/decisionaid.
- 29
30
31 561 20. Clarke V, Braun V, Hayfield N. Thematic analysis. *Qualitative psychology: A practical*
32
33 562 *guide to research methods*. 2015:222-48.
- 34
35 563 21. Microsoft Corporation. Microsoft Excel [Internet]. 2018. Available from:
36
37 564 <https://office.microsoft.com/excel>.
- 38
39
40 565 22. Joseph-Williams N, Newcombe R, Politi M, Durand MA, Sivell S, Stacey D, et al.
41
42 566 Toward Minimum Standards for Certifying Patient Decision Aids: A Modified Delphi
43
44 567 Consensus Process. *Med Decis Making*. 2014;34(6):699-710.
- 45
46
47 568 23. Witteman HO, Vaisson G, Provencher T, Chipenda Dansokho S, Colquhoun H, Dugas
48
49 569 M, et al. An 11-Item Measure of User- and Human-Centered Design for Personal Health Tools
50
51 570 (UCD-11): Development and Validation. *J Med Internet Res*. 2021;23(3):e15032.
- 52
53
54 571 24. Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain.
55
56 572 *Cochrane Database Syst Rev*. 2003(1):CD004016.
- 57
58
59
60

- 1
2
3 573 25. Page MJ, Green S, McBain B, Surace SJ, Deitch J, Lyttle N, et al. Manual therapy and
4
5 574 exercise for rotator cuff disease. *Cochrane Database Syst Rev*. 2016(6):CD012224.
6
7
8 575 26. Page MJ, Green S, Mrocki MA, Surace SJ, Deitch J, McBain B, et al. Electrotherapy
9
10 576 modalities for rotator cuff disease. *Cochrane Database Syst Rev*. 2016(6):CD012225.
11
12 577 27. Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug
13
14 578 benefits and harms: two randomized trials. *Ann Intern Med*. 2009;150(8):516-27.
15
16
17 579 28. Waldron C-A, van der Weijden T, Ludt S, Gallacher J, Elwyn G. What are effective
18
19 580 strategies to communicate cardiovascular risk information to patients? A systematic review.
20
21 581 *Patient Educ Couns*. 2011;82(2):169-81.
22
23
24 582 29. Zadro JR, Traeger AC, Décary S, O'Keeffe M. Problem with patient decision aids. *BMJ*
25
26 583 *Evid Based Med*. 2020 (Epub ahead of print).
27
28
29 584
30
31 585

Table 1. Characteristics of health professionals who manage people with shoulder pain (n=26) and people with shoulder pain (n=14)

Health professionals	Mean (SD) or N (%) (unless specified otherwise)
Profession	
<i>Physiotherapist</i>	11 (42%)
<i>Orthopaedic surgeon</i>	7 (27%)
<i>General practitioner</i>	4 (15%)
<i>Chiropractor</i>	3 (12%)
<i>Osteopath</i>	1 (4%)
Age (years)	40 (11)
Female	8 (31%)
Country of practice	
<i>Australia</i>	18 (69%)
<i>United States</i>	4 (15%)
<i>Canada</i>	2 (8%)
<i>England</i>	2 (8%)
Years of experience	12 (9)
Works in private practice	19 (73%)
Number of patients with shoulder pain seen per year	164 (167) Median (IQR): 100 (40-250)
People with shoulder pain	Mean (SD) or N (%) (unless specified otherwise)
Age (years)	46 (18)
Female	6 (43%)
Highest level of education	
<i>University</i>	6 (43%)
<i>High school or TAFE/Trade</i>	8 (57%)
Country of birth	
<i>Australia</i>	10 (71%)
<i>Philippines</i>	1 (7%)
<i>United States</i>	1 (7%)
<i>United Kingdom</i>	1 (7%)
<i>Egypt</i>	1 (7%)
Employment status	
<i>Working</i>	9 (64%)
<i>Not working</i>	3 (21%)
<i>Retired/unable to work</i>	2 (14%)
Health insurance	8 (57%)
Duration of shoulder pain (months)	96 (117) Median (IQR): 18 (6-180)
Activity interference in the past week	
<i>Not at all</i>	3 (21%)
<i>A little bit</i>	3 (21%)
<i>Moderately</i>	6 (43%)

	<i>Quite a bit</i>	1 (7%)
	<i>Extremely</i>	1 (7%)
Management strategies trialled		
	<i>Exercise</i>	9 (64%)
	<i>Medication</i>	8 (57%)
	<i>Rest</i>	7 (50%)
	<i>Massage</i>	6 (43%)
	<i>Manual therapy</i>	5 (36%)
	<i>Injections</i>	2 (14%)
	<i>Surgery</i>	2 (14%)
	<i>Other</i>	3 (21%)
	Previously had a scan (X-Ray, MRI, Ultrasound)	8 (57%)
	Previously had sick leave due to shoulder pain	2 (14%)

586 IQR: interquartile range; MRI: magnetic resonance imaging; N: number of participants; SD:
 587 standard deviation.

588

589

Table 2. Acceptability questionnaire for health professionals who manage patients with shoulder pain (n=15; nine physiotherapists, five orthopaedic surgeons and one osteopath)

Acceptability statements	Strongly agree, N (%)	Somewhat agree, N (%)	Neither agree nor disagree, N (%)	Somewhat disagree, N (%)	Strongly disagree, N (%)	Mean (SD)*	Mean (SD) for orthopaedic surgeons*
It will be easy for me to use	10 (67%)	4 (27%)	0 (0%)	0 (0%)	1 (7%)	4.5 (1.1)	3.6 (1.5)
It is easy for me to understand	12 (80%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	4.8 (0.4)	4.8 (0.4)
It will be easy for me to experiment with using it before making a final decision to adopt it	12 (80%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	4.8 (0.4)	4.6 (0.5)
The results of using the decision aid will be easy to see	2 (13%)	4 (27%)	7 (47%)	2 (13%)	0 (0%)	3.4 (0.9)	2.6 (0.5)
This decision aid is better than how I usually go about helping patients decide about shoulder surgery	3 (20%)	4 (27%)	4 (27%)	4 (27%)	0 (0%)	3.4 (1.1)	2.8 (0.8)
This decision aid is compatible with the way I think subacromial shoulder pain should be managed	8 (53%)	5 (33%)	2 (13%)	0 (0%)	0 (0%)	4.4 (0.7)	4.2 (0.4)
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	4 (27%)	5 (33%)	4 (27%)	2 (13%)	0 (0%)	3.7 (1.0)	3.6 (0.5)

Using this decision aid will save me time	2 (13%)	7 (47%)	4 (27%)	1 (7%)	1 (7%)	3.5 (1.1)	3.4 (1.5)
This decision aid is a reliable method of helping patients make decisions about shoulder surgery	7 (47%)	4 (27%)	1 (7%)	3 (20%)	0 (0%)	4.0 (1.2)	3.4 (1.3)
Pieces or components of the decision aid can be used by themselves	7 (47%)	7 (47%)	0 (0%)	1 (7%)	0 (0%)	4.3 (0.8)	4.2 (1.3)
This type of decision aid is suitable for helping patients make value laden choices	9 (60%)	4 (27%)	2 (13%)	0 (0%)	0 (0%)	4.5 (0.7)	4.2 (0.8)
This decision aid complements my usual approach	8 (53%)	4 (27%)	2 (13%)	1 (7%)	0 (0%)	4.3 (1.0)	3.8 (1.1)
Using this decision aid does not involve making major changes to the way I usually do things	10 (67%)	2 (13%)	2 (13%)	1 (7%)	0 (0%)	4.4 (1.0)	4.6 (0.5)
There is a high probability that using this decision aid may cause/result in more benefit than harm	4 (27%)	8 (53%)	2 (13%)	1 (7%)	0 (0%)	4.0 (0.8)	3.6 (0.9)

590 IQR: interquartile range; N: number of participants; SD: standard deviation.

591 *Likert Scale from strongly agree (5) to strongly disagree (1).

592

Table 3. Acceptability questionnaire for people with shoulder pain (n=11)

Acceptability items	N (%)
Information presented was 'excellent or good'*	
<i>Subacromial shoulder pain: should I have surgery?</i>	9 (82%)
<i>Causes and symptoms of subacromial shoulder pain</i>	8 (73%)
<i>What are the treatment options covered in this decision aid? (Non-surgical options)</i>	10 (91%)
<i>What are the treatment options covered in this decision aid? (Surgery)</i>	9 (82%)
<i>What are the likely benefits of surgery and non-surgical options?</i>	9 (82%)
<i>What are the likely risks of surgery?</i>	8 (73%)
<i>What practical issues should I consider?</i>	10 (91%)
<i>Questions to consider when talking with your health professional</i>	10 (91%)
Length of the decision aid	
<i>Just right</i>	8 (73%)
<i>Too short</i>	1 (9%)
<i>Too long</i>	2 (18%)
Amount of information	
<i>Just right</i>	10 (91%)
<i>Too little information</i>	0 (0%)
<i>Too much information</i>	1 (9%)
Presentation	
<i>Balanced</i>	2 (18%)
<i>Slanted towards surgery</i>	1 (9%)
<i>Slanted towards non-surgical options</i>	8 (73%)
Useful when deciding about surgery	11 (100%)
Makes decision to have surgery easier	8 (73%)
Enough information provided	9 (82%)

593 N: number of participants.

594 *compared to 'fair/poor'

595

596

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

597 **Figure legends**

598 Figure 1. Flowchart of the development process

599

For peer review only

1
2
3 **600 Supplementary files**
4

5 601 Supplementary File 1. Draft patient decision aid.
6

7 602 Supplementary File 2. Consolidated Criteria for Reporting Qualitative Research (COREQ)
8 checklist.
9

10 603
11 604 Supplementary File 3. Health professional questionnaire.
12

13 605 Supplementary File 4. Patient questionnaire.
14

15 606 Supplementary File 5. Topic guide for interviews with health professionals.
16

17 607 Supplementary File 6. Topic guide for interviews with patients.
18

19 608 Supplementary File 7. Acceptability questionnaire for health professionals.
20

21 609 Supplementary File 8. Acceptability questionnaire for patients.
22

23 610 Supplementary File 9. Patient decision aid.
24

25 611 Supplementary File 10. International Patient Decision Aid Standards (IPDAS) checklist.
26

27 612 Supplementary File 11. User-Centered Design 11-item measure (UCD-11)
28

29 613 Supplementary File 12. Themes, sub-themes and example quotes for each section of the
30 decision aid.
31

32 614
33 615 Supplementary File 13. Reasons for not implementing feedback for each section of the decision
34 aid.
35

36 616
37 617 Supplementary File 14. Changes between the first and final draft of 'Who should read this
38 decision aid?'
39

40 618
41 619 Supplementary File 15. Changes between the first and final draft of 'What are the treatment
42 options covered in this decision aid?'
43

44 620
45 621 Supplementary File 16. Changes between the first and final draft of 'What are the likely
46 benefits of surgery compared to non-surgical options?'
47

48 622
49 623 Supplementary File 17. Changes between the first and final draft of 'What are the likely harms
50 of surgery?'
51

52 624
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

625 Supplementary File 18. Changes between the first and final draft of ‘Summary of benefits,
626 harms, and other practical issues.’

627 Supplementary File 19. Changes between the first and final draft of ‘Questions to consider
628 when talking with a health professional.’

629

630

631

For peer review only

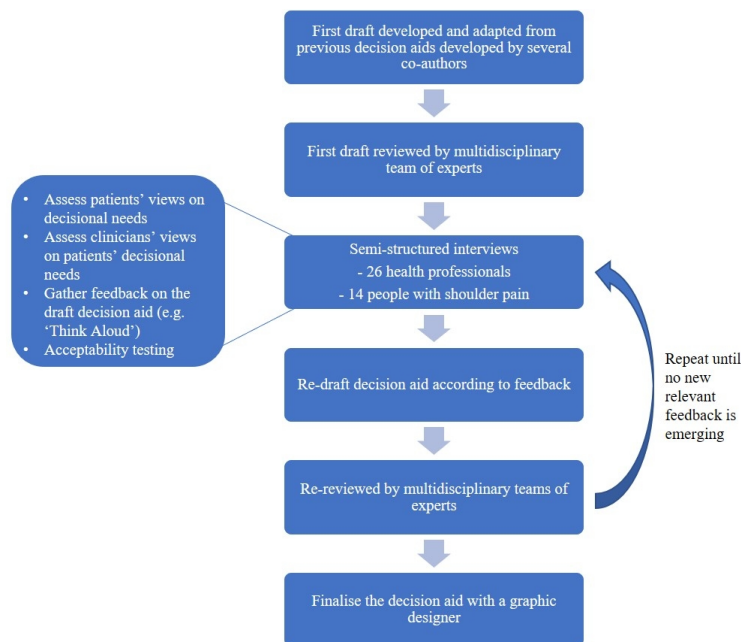


Figure 1. Flowchart of the development process

225x143mm (150 x 150 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

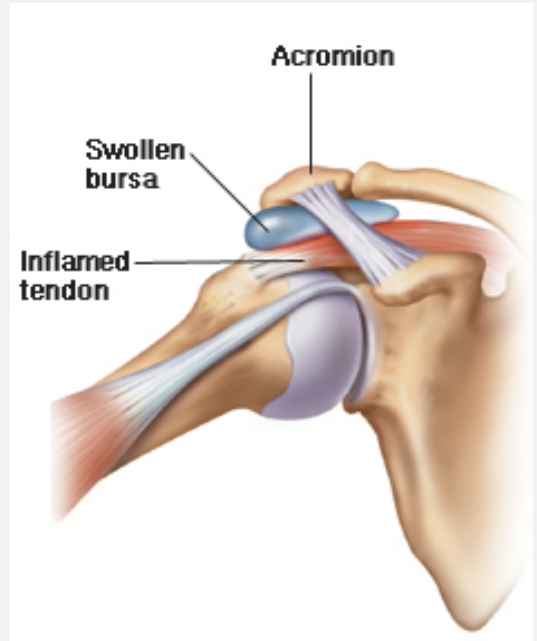
Shoulder pain: should I have arthroscopic surgery?

Is this decision aid relevant for me?

- This decision aid can help if you have shoulder pain due to common causes like rotator cuff tears or bursitis and are considering arthroscopic surgery of the shoulder

Cause and symptoms of shoulder pain

- **Shoulder pain** is commonly caused by rotator cuff tears, swelling of fluid filled sacs call bursa ('bursitis') or impingement.
- Impingement occurs due to contact between a bony part of the shoulder (the 'acromion') and the rotator cuff tendons or bursa (see picture). Contact usually occurs as you move your arm out to the side.
- Shoulder pain often makes it difficult to do simple everyday tasks like reaching into a high cupboard and washing hair.
- Symptoms often take time to settle and one half of patients are better by around 6 months.



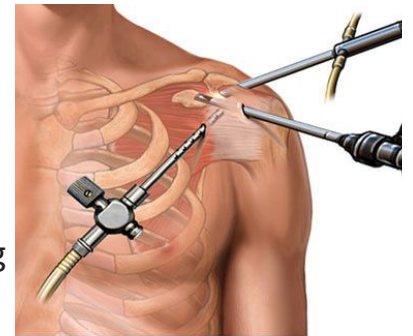
What are the treatment options covered in this decision aid?

1. Surgery ('subacromial decompression' and/or 'rotator cuff repair')

Surgery requires admission to hospital and an anaesthetic. The surgeon will make a small skin cut in your shoulder to perform the procedure. Your surgeon may perform one or both of the following procedures:

- **Subacromial decompression:** Increase the space under the acromion by either shaving back some bone, trimming some ligament or removing a bursa
- **Rotator cuff repair:** Reconnecting torn rotator cuff tendons

The surgeon may only decide on which procedure to perform while in surgery.



2. No surgery

You can choose to not have surgery and instead have injections, physiotherapy, medication or wait to see if it improves by itself.



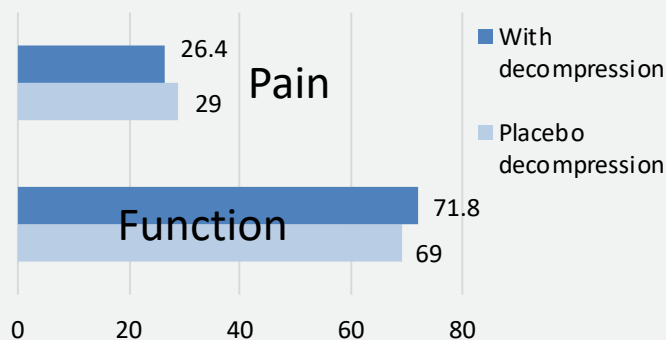
What are the likely benefits of arthroscopic surgery and non-surgical options?

Subacromial decompression vs. placebo

HIGH CERTAINTY EVIDENCE* that subacromial decompression is little-to-no better than placebo...

***We are very confident that the figures below represent the true benefits of surgery**

Placebo = the patient goes under anaesthetic and the surgeon inserts the surgical tools BUT no further procedure is performed



KEY MESSAGE: On average, surgery leads to **2.6% less pain** and **2.8% better function** compared to placebo surgery at 12 months.

Most patients would not consider these benefits important.

What % of people report treatment success?

treatment success rated by patients

treatment not a success

Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



71 out of 100 report success

Placebo



66 out of 100 report success

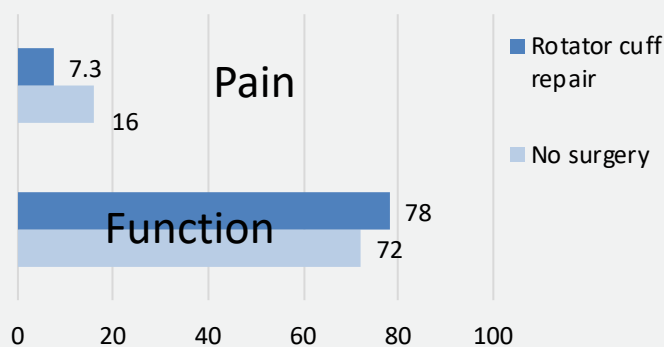
With surgery, **5 more people out of 100** will report their treatment as successful at 12 months.

Rotator cuff repair vs. no surgery

LOW-MODERATE CERTAINTY EVIDENCE* that rotator cuff repair is little-to-no better than no surgery...

***We have low-moderate confidence that the figures below represent the true benefits of surgery**

No surgery = injections, physiotherapy, medication or no treatment



KEY MESSAGE: On average, surgery leads to **8.7% less pain** and **6% better function** compared to no surgery at 12 months.

Most patients would not consider these benefits important.

What % of people report treatment success?

treatment success rated by patients

treatment not a success

Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



95 out of 100 report success

No surgery

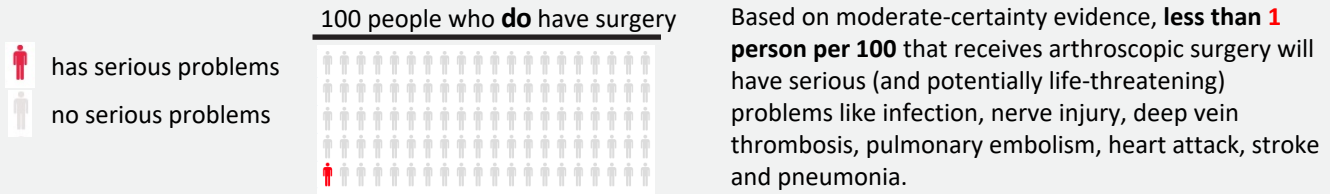


87 out of 100 report success

With surgery, **8 more people out of 100** will report their treatment as successful at 12 months.

What are the likely **harms** of arthroscopic surgery?

Each figure represents one person. We can't predict whether you will be one of the people who is harmed.



Where do these estimates of **benefits** and **harms** come from?

Estimates of benefits and harms are based on the most up-to-date medical evidence from two reviews of 17 studies and over 2000 people that looked at arthroscopic surgery in people with subacromial pain syndrome.

What practical issues should I consider?

The table shows key practical issues for those who have arthroscopic surgery and those who do not.

	ARTHROSCOPIC SURGERY	NO SURGERY
Procedure and follow-up	Performed by a surgeon in an operating theatre. Requires an anesthetic. Individualised follow-up with wound care and exercise	Advice from a professional about other treatments may be useful (eg. injections, exercise, activity modification, medication)
Recuperation	You may use a sling a few days after surgery. Recuperation typically takes between 2-6 weeks	No recuperation needed
Activity restrictions	Avoid heavy lifting for 7-21 days, overhead activities for 6 weeks and pushing through your hands for 3 months	No activity restrictions
Time off work	Depends on recovery and demands of job. Usually a few weeks after surgery	No time off work
Driving	You can start driving as soon as you feel able to steer. This is normally after one week	No driving limitations
Costs	Out-of-pocket costs for surgery are generally high. There may also be out-of-pocket costs for physiotherapy after surgery	No surgical costs BUT there may be out-of-pocket costs for physiotherapy or injections

Are there other things I can do?

- Strength and endurance exercises for your shoulder might help reduce pain and improve function.
- Modifying your activities and using pain relieving medicines when needed might help reduce pain.
- Seek advice from a health professional about the options that best suit your needs.
- Consider surgery at a later point if the above points do not help

Questions to consider when talking with your doctor...

- Do I need arthroscopic surgery?
- What happens if I don't have arthroscopic surgery?
- Do I know enough about the benefits and harms of:
 - » having arthroscopic surgery of the shoulder?
 - » not having arthroscopic surgery?
- Am I clear about which benefits and harms matter most to me?
- Do I have enough information and support to decide?

References

1. Karjalainen TV, et al. Subacromial decompression surgery for rotator cuff disease. Cochrane Database of Systematic Reviews 2019, Issue 1. Art. No.: CD005619.
2. Karjalainen TV, et al. Surgery for rotator cuff tears. Cochrane Database of Systematic Reviews 2019, Issue 1. Art. No.: CD001350.

The information in this education pamphlet is provided for general information only. It is not intended as medical advice and should not be relied upon as a substitute for consultations with a qualified health professional who can determine your medical needs.

Last reviewed: ... 2019. Update due ... 2020. Developed by Dr Joshua Zadro, ... [Institute for Musculoskeletal Health, School of Public Health, The University of Sydney, NSW, Australia.

Supplementary File 2. Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Items	Guide questions/description	Yes/No
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Yes
Credentials	What were the researcher's credentials? e.g., PhD, MD	Yes
Occupation	What was their occupation at the time of the study?	Yes
Gender	Was the researcher male or female?	Yes
Experience and training	What experience or training did the researcher have?	Yes
Relationship established	Was a relationship established prior to study commencement?	Yes
Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	Yes
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic	Yes
Methodological orientation and theory	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Yes
Sampling	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Yes
Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Yes
Sample size	How many participants were in the study?	Yes
Non-participation	How many people refused to participate or dropped out? Reasons?	Yes
Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Yes
Presence of non-participants	Was anyone else present besides the participants and researchers?	Yes
Description of sample	What are the important characteristics of the sample? e.g., demographic data, date	Yes
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Yes
Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes
Field notes	Were field notes made during and/or after the interview or focus group?	Yes
Duration	What was the duration of the interviews or focus group?	Yes
Data saturation	Was data saturation discussed?	Yes

1 2 3 4 5	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Yes
6 7 8	Number of data coders	How many data coders coded the data?	Yes
9 10	Description of the coding tree	Did authors provide a description of the coding tree?	Yes
11 12	Derivation of themes	Were themes identified in advance or derived from the data?	Yes
13	Software	What software, if applicable, was used to manage the data?	Yes
14	Participants checking	Did participants provide feedback on the findings?	Yes
15 16 17	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Yes
18 19 20	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
21 22 23	Clarity of major themes	Were major themes clearly presented in the findings?	Yes
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Supplementary File 3. Health professional questionnaire

Thank you for your participation in this study, which is investigating what information health professionals feel patients need to know when considering shoulder surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-10 minutes.

First some quick questions about you...

1. Please indicate your gender:

- Female
- Male
- Prefer not to say

2. Please indicate your age: [free text response]

3. In which country do you currently practice? [free text response]

4. What health profession are you?

- Orthopaedic surgeon
- General practitioner
- Rheumatologist
- Sports medicine doctor
- Physiotherapist
- Other (please specify) _____

5. How many years have you been practicing? [free text response]

6. Which clinical setting have you spent the most time practicing in?

- Private practice
- Public hospital
- Private hospital
- Sports teams
- Other (please specify) _____

7. On average, how many patients with subacromial pain syndrome do you manage/review per year? [free text response]

Thank you for completing the questionnaire.

Supplementary File 4. Patient questionnaire

Thank you for your participation in this study, which is investigating what information patients feel is important to know when considering shoulder surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-10 minutes.

First some quick questions about you...

1. Please indicate your gender:

- Female
- Male
- Prefer not to say

2. Please indicate your age: [free text response]

3. In which country were you born? [free text response]

4. What option best describes your highest level of education?

- Primary school or less
- High school (not completed)
- High school (completed)
- TAFE/Trade
- University- undergraduate degree/s (completed)
- University- postgraduate degree/s e.g. Masters, PhD (completed)
- Other (please specify) _____

5. What is your employment status?

- Employed part-time
- Employed full-time
- Casual work
- Retired
- Unemployed
- Student
- Sick/disability leave
- Other (please specify) _____

6. Do you have private health insurance?

- Yes
- No

7. How long have you had your shoulder pain (in weeks, months or years)?

8. During the past week, how much did shoulder pain interfere with your normal work (including both work outside the home and housework)?

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- Not at all
 A little bit
 Moderately
 Quite a bit
 Extremely
9. What treatment options have you tried for you shoulder pain?
- Rest
 Medication
 Exercise
 Massage
 Manual therapy (usually provided by a physiotherapist)
 Injections
 Surgery
 Other (please specify) _____
10. Have you previously had a scan on your affected shoulder (e.g Xray, ultrasound, MRI)?
- Yes
 No
11. Have you previously taken sick leave due to shoulder pain?
- Yes
 No
12. If you have had shoulder surgery, please specify the procedure (i.e. rotator cuff repair, shaving back a bone spur, removal of bursa) [free text response]
- _____

Thank you for completing the questionnaire.

Supplementary File 5. Topic guide for interviews with health professionals.

Example structure of interviews with health professionals

Note: The topics below will serve as an outline to guide the interview

Introductions

- Group introductions
- Brief explanation of the interview

Opening questions

- What is your understanding of subacromial pain syndrome? What causes it? How can it be treated?
- What information is important to know about different treatments?
- What do you think of surgery (specifically subacromial decompression and rotator cuff repair surgery) as a treatment?

Brief explanation of subacromial decompression and rotator cuff repair surgery to health professionals (depending on their current level of understanding e.g. do not explain this to an orthopedic surgeon)

- Nature of the procedure
- Theoretical indications
- Benefits and harms

Core questions

If we were designing an education leaflet to help patients decide whether to have subacromial decompression surgery or not....

- What information is most important for them to know? (prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure, etc.)
- How would you like information to be presented in terms of visual aids, text, tables, pictures, etc.? (example below, but exact topics will depend on what arose from the previous question)
 - Different treatment options
 - Benefits and harms
 - Recovery time
 - Likelihood of need for revision surgery
 - Details of the procedure
- How would your response to the above options differ if the information was intended to be used during a consultation with a health professional?

When reviewing patient decision aid

Instructions to health professionals (as an example): The material we want you to review has been developed for patients to improve their knowledge and confidence in making the decision to have shoulder surgery or not. We would like for you to help us refine this material – for example, how you find the visual appeal, readability, content, and what are your overall thoughts on patients using this material?

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything confusing, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. “look at a table”, “look at a page with just text vs with an image”).

Prompt questions as health professionals are reading through the material:

- How do you think patients would find this section?
- Did you feel like patients will know where to look, and what to do next?

- 1 • Did you feel like patients knew the relevance of this section in their decision?
- 2
- 3 • How do you think patients will find the content of this section?
- 4 • Were the instructions clear/helpful?
- 5 • How easy was it to understand the section? (readability)
- 6 • Was there anything that was unclear or confusing?
- 7 • How were the visual aids?
- 8 • How was the functionality?
- 9 • Is there anything that you would improve in this section?
- 10 • What did you like most about this material?
- 11 • What did you like least about this material?
- 12
- 13
- 14
- 15
- 16
- 17

18 **General feedback at the end**

- 19 • Are there any topics that you would like to see in future versions of this tool?
- 20 • Do you have any other general feedback, thoughts or comments?
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

Supplementary File 6. Topic guide for interviews with patients.

Example structure of interviews with patients

Note: The topics below will serve as an outline to guide the interview

Introductions

- Group introductions
- Brief explanation of the interview

Opening questions

- What is your understanding of your shoulder pain (i.e. subacromial pain syndrome)?
- How and why do you think this affects people?
- How can it be treated?
- What treatments have you heard of or been suggested to try?
- What information is important to know about different treatments?
- What would you like to know about the benefits?
- What would you like to know about harms?
- What do you think of surgery as a treatment?

Explain subacromial decompression surgery to patients

- Nature of the procedure
- Theoretical indications
- Benefits and harms

Core questions

If we were designing an education leaflet to help you decide whether to have subacromial decompression surgery or not....

- What information is most important to know? (prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure, etc.)
- How would you like information to be presented in terms of visual aids, text, tables, pictures, etc.?
(example below, but exact topics will depend on what arose from the previous question)
 - Different treatment options
 - Benefits and harms
 - Recovery time
 - Likelihood of need for revision surgery
 - Details of the procedure

When reviewing patient decision aid

Instructions to patients (as an example): The material we want you to review has been developed for patients to improve their knowledge and confidence in making the decision to have shoulder surgery or not. We would like for you to help us better understand your experience of this material – for example, how you find the visual appeal, readability, content, and what are your overall experiences using this material.

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything challenging, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. “look at a table”, “look at a page with just text vs with an image”).

Prompt questions as patients are reading through the material:

- How are you finding reading through this section?
- Did you feel like you knew where to look, and what to do next?

- 1 • Did you feel like you knew the relevance of this section in your decision?
- 2
- 3 • How did you find the content of this section?
- 4 • Were the instructions clear/helpful?
- 5 • How easy was it to understand the section? (readability)
- 6 • Was there anything that was unclear or confusing?
- 7 • How were the visual aids?
- 8 • How was the functionality?
- 9 • Is there anything that you would improve in this section?
- 10 • What did you like most about this material?
- 11 • What did you like least about this material?
- 12
- 13
- 14
- 15
- 16
- 17

18 **General feedback at the end**

- 19 • Are there any topics that you would like to see in future versions of this tool?
- 20 • Do you have any other general feedback, thoughts or comments?
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

Supplementary File 7. Acceptability questionnaire for health professionals

The following set of questions asks about your perceptions of the decision aid you just read. We are interested in your reactions to the decision aid. Please indicate how strongly you agree or disagree with each statement by *circling* the appropriate number.

In general:	Strongly agree		→		Strongly disagree
It will be easy for me to use	1	2	3	4	5
It is easy for me to understand	1	2	3	4	5
It will be easy for me to experiment with using it before making a final decision to adopt it	1	2	3	4	5
The results of using the decision aid will be easy to see	1	2	3	4	5
This decision aid is better than how I usually go about helping patients decide about shoulder surgery	1	2	3	4	5
This decision aid is compatible with the way I think subacromial shoulder pain should be managed	1	2	3	4	5
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	1	2	3	4	5
Using this decision aid will save me time	1	2	3	4	5
This decision aid is a reliable method of helping patients make decisions about shoulder surgery	1	2	3	4	5
Pieces or components of the decision aid can be used by themselves	1	2	3	4	5
This type of decision aid is suitable for helping patients make value laden choices	1	2	3	4	5
This decision aid complements my usual approach	1	2	3	4	5
Using this decision aid does not involve making major changes to the way I usually do things	1	2	3	4	5
There is a high probability that using this decision aid may cause/result in more benefit than harm	1	2	3	4	5

Supplementary File 8. Acceptability questionnaire for patients

We would like to know what you think about the patient decision aid you have just read.

1. Please rate each section by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Subacromial shoulder pain: should I have surgery?	Poor	Fair	Good	Excellent
Causes and symptoms of subacromial shoulder pain	Poor	Fair	Good	Excellent
What are the treatment options covered in this decision aid? (Non-surgical options)	Poor	Fair	Good	Excellent
What are the treatment options covered in this decision aid? (Surgery)	Poor	Fair	Good	Excellent
What are the likely benefits of surgery and non-surgical options? (Key message)	Poor	Fair	Good	Excellent
What are the likely benefits of surgery and non-surgical options? (What % of people report treatment success?)	Poor	Fair	Good	Excellent
What are the likely risks of surgery?	Poor	Fair	Good	Excellent
What practical issues should I consider?	Poor	Fair	Good	Excellent
Questions to consider when talking with your health professional	Poor	Fair	Good	Excellent

2. The length of the decision aid was (check one):
 - a. Too long
 - b. Too short
 - c. Just right
3. The amount of information was (check one):
 - a. Too much information
 - b. Too little information
 - c. Just right
4. I found the presentation (check one):
 - a. Slanted towards non-surgical options
 - b. Slanted towards surgery
 - c. Balanced
5. Would you find (or would you have found) this decision aid useful when /if you were making your decision about surgery for subacromial shoulder pain?
 - a. Yes
 - b. No
 - c. Comments:
6. Did this decision aid/would this decision aid make your decision to have surgery:
 - a. Easy

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- b. More difficult
 - c. Comments:
7. Do you think we provided enough information to help people with subacromial shoulder pain decide on whether to have surgery or not?
- a. Yes
 - b. No
 - c. Comments:

For peer review only

SHOULDER PAIN: SHOULD I HAVE SURGERY?

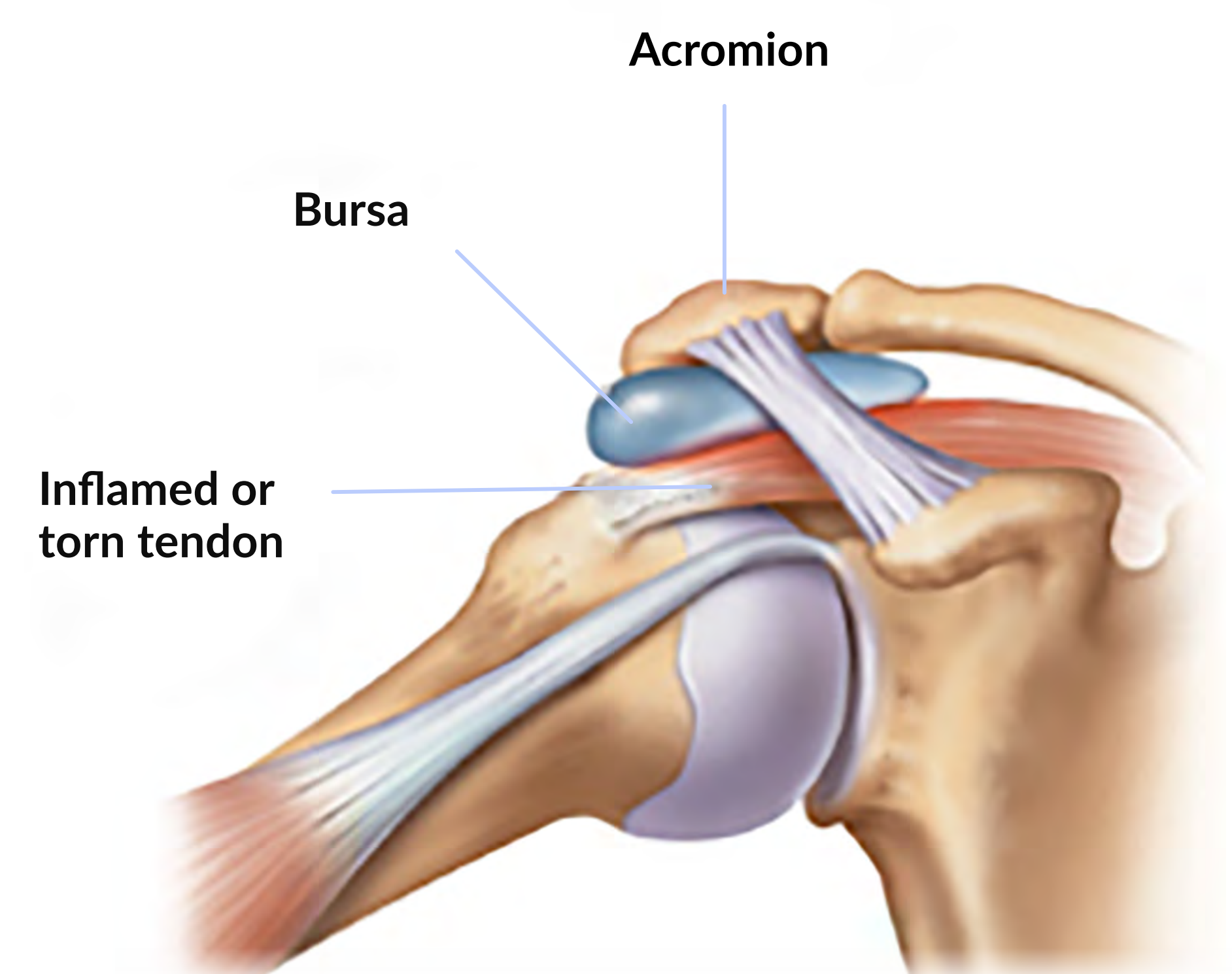
All information in this decision aid should be discussed with a health professional

+ Who should read this decision aid?

This decision aid is for people with persisting shoulder pain that is likely due to issues with rotator cuff tendons that move and support the shoulder (eg. inflammation, tears).

This type of pain often occurs around the shoulder. It makes it difficult to do simple tasks that involve lifting your arm above your head (eg. washing hair).

This decision aid does not apply to people who have other causes of shoulder pain like frozen shoulder (which causes pain and severe stiffness), osteoarthritis, or shoulder pain that begins after trauma immediately resulting in loss of movement or strength (eg. sudden rotator cuff tear, fracture, dislocation). If you're unsure of the cause of your pain, see a health professional.

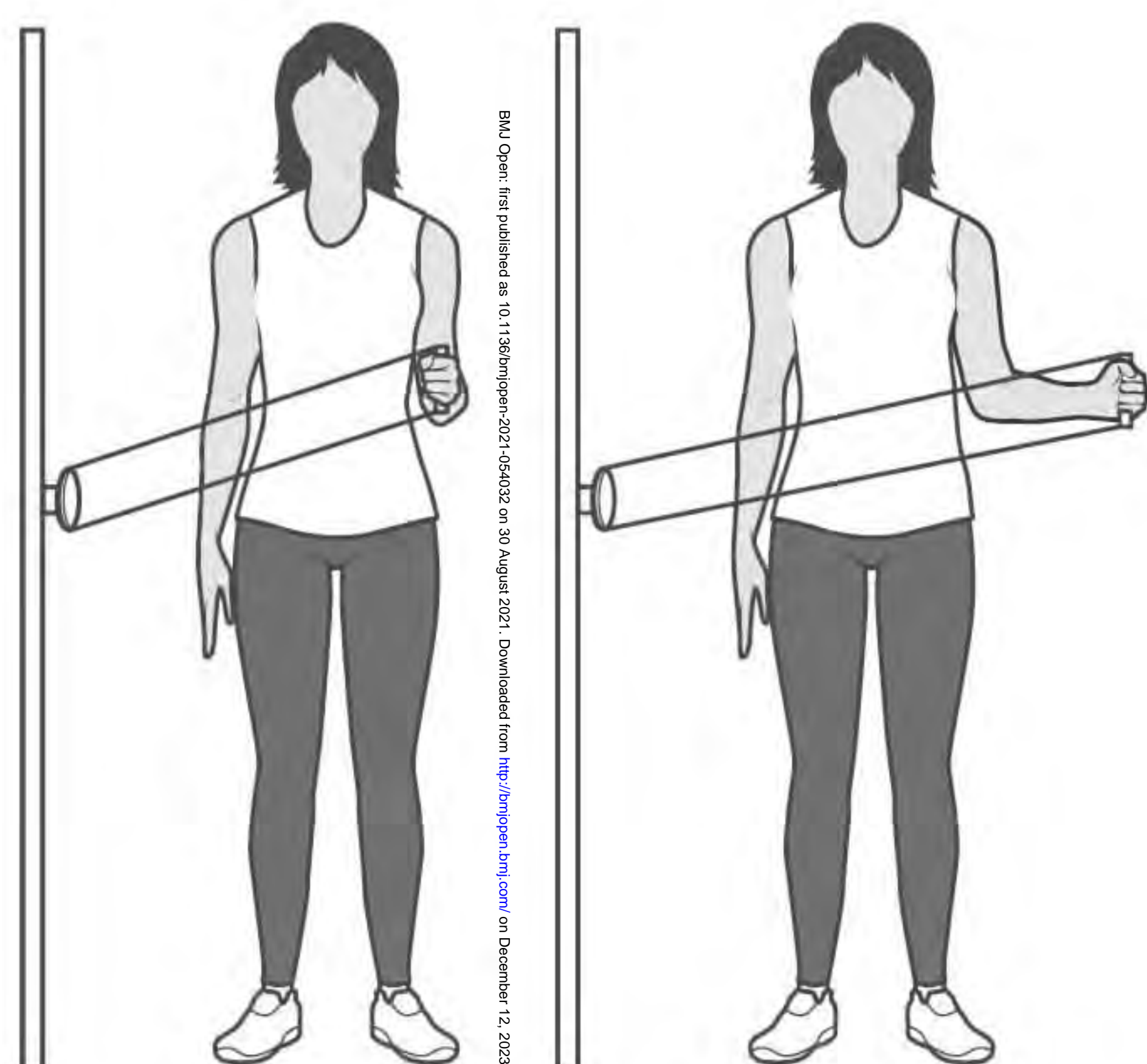


+ What are the treatment options covered in this decision aid?

NON-SURGICAL OPTIONS

Trying the following non-surgical options is recommended before considering surgery:

- Wait to see if your symptoms improve by themselves (roughly half of all people with these symptoms will recover within 6 months) and/or change your activities until the pain settles (eg. avoid carrying heavy grocery bags or take a break from sport if these activities cause pain)
- Take simple pain medicine (eg. paracetamol, anti-inflammatories)
- See a health professional (eg. physiotherapist) for advice on changing some daily activities and/or some muscle strength and endurance exercises
- See a health professional (eg. doctor) for a corticosteroid injection



SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

You may consider surgery if the non-surgical options do not work and you can no longer put up with the pain. Typically surgery is not performed unless you have had symptoms for at least 3-6 months.

Surgery requires staying in hospital, having an anaesthetic and small skin cuts in your shoulder so the surgeon can perform one or both of the following:

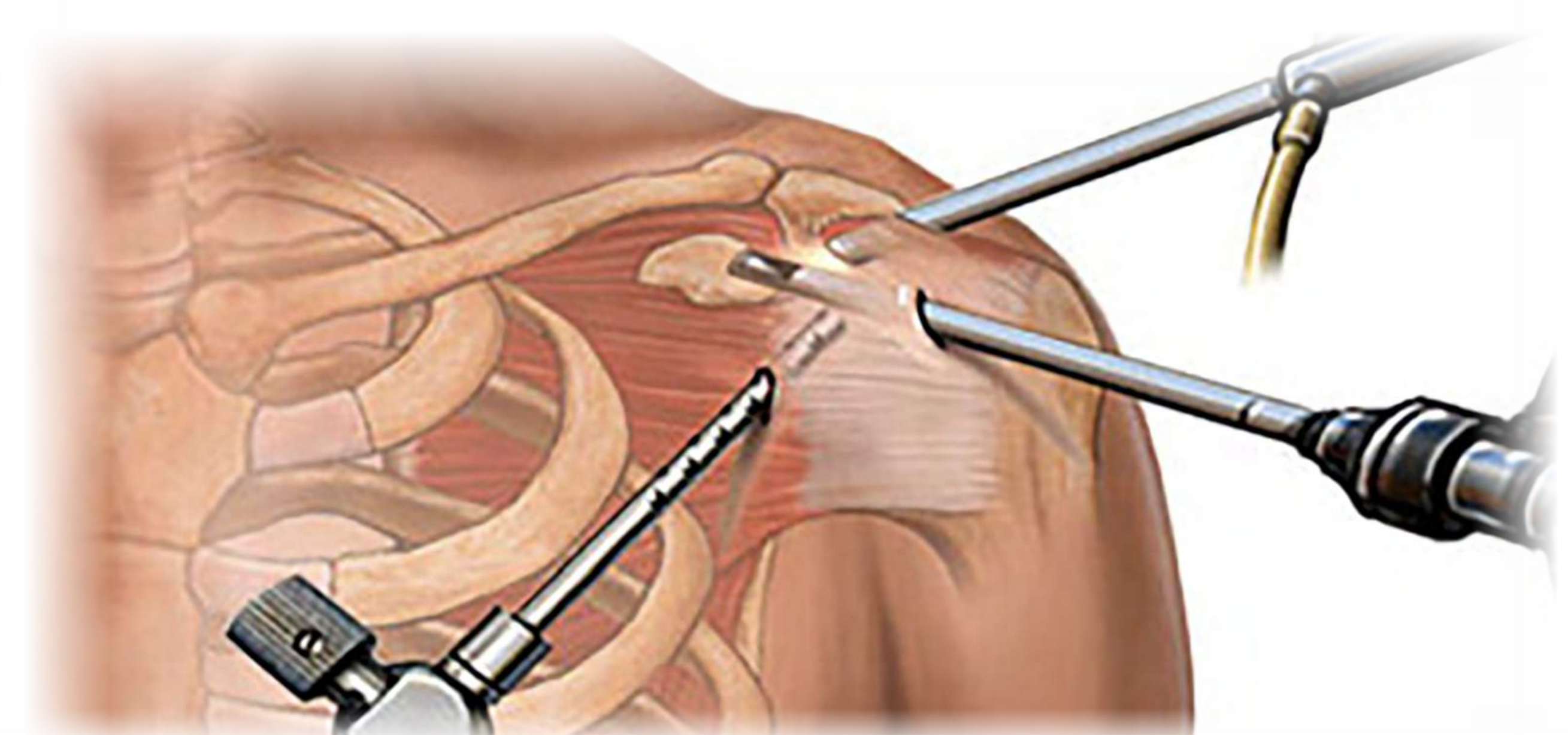
✓ Subacromial decompression surgery

Increase the space under the acromion by either shaving back some bone, trimming some ligament and/or removing a bursa

✓ Rotator cuff repair surgery

Reconnecting torn rotator cuff tendons

You will need to have rehabilitation involving exercises for at least 3 months following surgery. Much of this rehabilitation can be done at home.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

+ What are the likely benefits of surgery compared to non-surgical options?

The figures on this page are based on the most up-to-date medical research as of 2020 (see references at the bottom of this page)

KEY MESSAGE

On average, patients report that surgery **improves pain and function by less than 10%** (ie. an improvement in pain or function of less than a 1 point on a 0-10 pain scale) compared to non-surgical options in the short term (6 months after) and longer term (1-2 years after) ^c. Because most patients do not notice these improvements, research concludes:

- Subacromial decompression surgery is not better than placebo or non-surgical options (ie. injections, exercise, medication or no treatment) for people with shoulder pain and no full-thickness rotator cuff tears ^A
- Rotator cuff repair surgery is little-to-no better than non-surgical options for people with full-thickness rotator cuff tears ^B

These results are averages. Surgery improves pain and function by more than 10% for some patients. But other patients have either **no improvements or worse** pain and function after surgery.

Further information:

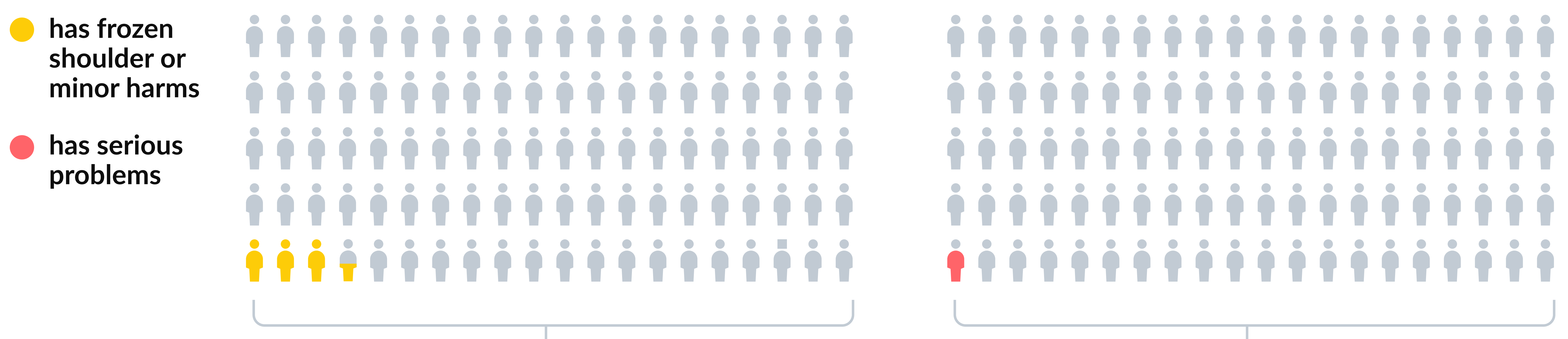
^A For subacromial decompression surgery, we are very confident about this key message because research on this surgery is high-quality. This research was mostly conducted on people aged in their 40s, 50s and 60s, but is the best evidence we have for all ages.

^B For rotator cuff repair surgery, we are somewhat confident about this message because there is lack of high-quality research on this surgery. This research was mostly conducted on people aged in their 50s and 60s but is the best evidence we have for all ages. Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon.

^C Research suggests exercise or activities that you can do yourself at home may be just as helpful as a supervised exercise program.

- What are the likely harms of surgery?

Think of each figure as 1 person. We can't predict if you will be one of the people who is harmed. Harms are more common among people with other health conditions (e.g. diabetes, heart disease).



About 3 people per 100 that have surgery will develop frozen shoulder (which may cause shoulder pain and stiffness for up to 2 years) or minor harms with surgery.

About 1 person per 100 that has surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, heart attack, stroke and pneumonia.

Important information: The information in this decision aid is not intended as medical advice and should not be used as a substitute to seeing a qualified health professional who can determine your medical needs.

References: 1) Karjalainen TV, et al. Cochrane Database Syst Rev. 2019, Issue 1. Art. No.: CD005619;
 2) Karjalainen TV, et al. Cochrane Database Syst Rev. 2019, Issue 12. Art. No.: CD013502;
 3) Page MJ, et al. Cochrane Database Syst Rev. 2016, Issue 6. Art. No.: CD012224.

+ Summary of benefits, harms, and other practical issues

NON-SURGICAL OPTIONS

✓ Potential benefits

- May **improve by itself** (within 6 months half of people will recover) or with non-surgical options (ie. injections, exercise, or medication)
- **Avoid surgery**

− Potential harms

- May decide to **have surgery later**
- **Cost of non-surgical options** (eg. injection, physiotherapy)
- **Time to attend health appointments** (eg. for physiotherapy)
- Regardless of what treatment you have, your symptoms **may not improve**

SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

✓ Potential benefits

- May provide **slight improvement in pain and function** compared to non-surgical options

− Potential harms

- Possible **surgical harms** (eg. frozen shoulder, infection)
- Your symptoms **may not improve** with surgery
- **Symptoms will temporarily be worse after surgery** due to the operation (eg. pain when sleeping or moving your arm)
- **Rehabilitation for 3-12 months** after surgery and time to attend rehabilitation
- May take up to **6 weeks** after subacromial decompression and **12 weeks** after rotator cuff repair to perform daily activities (eg. reach above your head, lift heavy objects)
- May take **3-4 months** after subacromial decompression and **6-12 months** after rotator cuff repair to return to heavy manual work, exercise, or sport
- **Out-of-pocket costs** are generally higher for surgery than non-surgical options. There may be **costs for rehabilitation** after surgery and due to **time needed off work**

+ Questions to consider when talking with a health professional...

- 🔍 Do I need surgery? What happens if I don't have surgery? What happens if I do nothing?
- 📊 Is surgery suitable for me? Which surgery is suitable for my diagnosis?
- 👤 Can I have surgery later? If so, how long should I wait before considering surgery?
- ➕ Have I considered my situation before making any decisions (eg. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport, etc)?
- 🏥 Do I understand enough about my condition and the benefits and harms of having surgery and not having surgery?



Discloser: Arthritis Australia provided funding to develop this tool but had no involvement in the development process. The developers of this decision aid include orthopaedic surgeons, rheumatologists, physiotherapists, psychologists and occupational therapists, who have a range of views on the information in this decision aid. 8/11 developers have a PhD. None of the developers will gain or lose anything based on the choices that people make. Feedback from people with shoulder pain and health professionals practicing in various countries was used to refine the information presented in this decision aid.

Last reviewed: 27/05/21. Update due 27/05/23.

Lead developer: Dr Joshua Zdro, Institute for Musculoskeletal Health, University of Sydney, Australia.

Supplementary File 10. International Patient Decision Aid Standards checklist (IPDASi v4.0)

Qualifying criteria	Answer
1. The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required.	Yes
2. The patient decision aid explicitly states the decision that needs to be considered (index decision).	Yes
3. The patient decision aid describes the options available for the index decision.	Yes
4. The patient decision aid describes the positive features (benefits or advantages) of each option.	Yes
5. The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option.	Yes
6. The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	Yes
Certification criteria	Answer
1. The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	Yes
2. The patient decision aid (or associated documentation) provides citations to the evidence selected.	Yes
3. The patient decision aid (or associated documentation) provides a production or publication date.	Yes
4. The patient decision aid (or associated documentation) provides information about the update policy.	Yes
5. The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as “our best estimate is . . .”).	Yes
6. The patient decision aid (or associated documentation) provides information about the funding source used for development.	Yes
7. The patient decision aid describes what the test is designed to measure.	N/A
8. If the test detects the condition or problem, the patient decision aid describes the next steps typically taken.	N/A
9. The patient decision aid describes the next steps if the condition or problem is not detected.	N/A
10. The patient decision aid has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).	N/A
Quality criteria	Answer
1. The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate).	Yes
2. The patient decision aid makes it possible to compare the positive and negative features of the available options.	Yes
3. The patient decision aid provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions).	Yes
4. The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply.	Yes

5. The patient decision aid specifies the event rates for the outcome probabilities	Yes
6. The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	Yes
7. The patient decision aid allows the user to compare outcome probabilities across options using the same denominator (when feasible).	Yes
8. The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams).	Yes
9. The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly).	Yes
10. The patient decision aid provides a step-by step way to make a decision.	Yes
11. The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	Yes
12. The development process included a needs assessment with clients or patients.	Yes
13. The development process included a needs assessment with health professionals.	Yes
14. The development process included review by clients/patients not involved in producing the decision support intervention.	Yes
15. The development process included review by professionals not involved in producing the decision support intervention.	Yes
16. The patient decision aid was field tested with patients who were facing the decision.	Yes
17. The patient decision aid was field tested with practitioners who counsel patients who face the decision.	Yes
18. The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	Yes
19. The patient decision aid (or associated documentation) describes the quality of the research evidence used.	Yes
20. The patient decision aid includes authors'/developers' credentials or qualifications.	Yes
21. The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	No
22. There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	No*
23. There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	No*
24. The patient decision aid includes information about the chances of having a true-positive test result.	N/A
25. The patient decision aid includes information about the chances of having a true-negative test result.	N/A
26. The patient decision aid includes information about the chances of having a false-positive test result.	N/A
27. The patient decision aid includes information about the chances of having a false-negative test result.	N/A
28. The patient decision aid describes the chances the disease is detected with and without the use of the test.	N/A

1
2
3 N/A: not applicable.

4 *we are in the process of evaluating the decision aid in a randomised controlled trial.
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Supplementary File 11. User-Centered Design 11-item measure (UCD-11)

Items	Explanations and examples	Yes/No
1. Were potential end users (eg, patients, caregivers, family and friends, surrogates) involved in any steps to help understand users (eg, who they are, in what context might they use the tool) and their needs?	Such steps could include various forms of user research, including formal or informal needs assessment, focus groups, surveys, contextual inquiry, ethnographic observation of existing practices, literature review in which users were involved in appraising and interpreting existing literature, development of user groups, personas, user profiles, tasks, or scenarios, or other activities	Yes
2. Were potential end users involved in any steps of designing, developing, and/or refining a prototype?	Such steps could include storyboarding, reviewing the draft design or content before starting to develop the tool, and designing, developing, or refining a prototype	Yes
3. Were potential end users involved in any steps intended to evaluate prototypes or a final version of the tool?	Such steps could include feasibility testing, usability testing with iterative prototypes, pilot testing, a randomized controlled trial of a final version of the tool, or other activities	Yes
4. Were potential end users asked their opinions of the tool in any way?	For example, they might be asked to voice their opinions in a focus group, interview, survey, or through other methods	Yes
5. Were potential end users observed using the tool in any way?	For example, they might be observed in a think-aloud study, cognitive interviews, through passive observation, logfiles, or other methods	Yes
6. Did the development process have 3 or more iterative cycles?	The definition of a cycle is that the team developed something and showed it to at least one person outside the team before making changes; each new cycle leads to a version of the tool that has been revised in some small or large way	Yes
7. Were changes between iterative cycles explicitly reported in any way?	For example, the team might have explicitly reported them in a peer-reviewed paper or in a technical report. In the case of rapid prototyping, such reporting could be, for example, a list of design decisions made and the rationale for the decisions	No
8. Were health professionals asked their opinion of the tool at any point?	Health professionals could be any relevant professionals, including physicians, nurses, allied health providers, etc. These professionals are not members of the research team. They provide care to people who are likely users of the tool. Asking for their opinion means simply asking for feedback, in contrast to, for example, observing their interaction with the tool or assessing the impact of the tool on health professionals' behavior	Yes

1			
2			
3	9. Were health professionals	Consulting before the first prototype means	Yes
4	consulted before the first	consulting prior to developing anything. This	
5	prototype was developed?	may include a variety of consultation methods	
6			
7	10. Were health	Consulting between initial and final prototypes	Yes
8	professionals consulted	means some initial design of the tool was	
9	between initial and final	already created when consulting with health	
10	prototypes?	professionals	
11			
12	11. Was an expert panel	An expert panel is typically an advisory panel	Yes
13	involved?	composed of experts in areas relevant to the	
14		tool if such experts are not already present on	
15		the research team (eg, plain language experts,	
16		accessibility experts, designers, engineers,	
17		industrial designers, digital security experts,	
18		etc). These experts may be health professionals	
19		but not health professionals who would	
20		provide direct care to end users	
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			
41			
42			
43			
44			
45			
46			
47			
48			
49			
50			
51			
52			
53			
54			
55			
56			
57			
58			
59			
60			

Supplementary File 12. Themes, sub-themes and example quotes for each section of the decision aid.

Themes	Sub-themes	Example quotes (abbreviation for type of health professional comes first, where applicable)
WHO SHOULD READ THIS DECISION AID?		
Positive feedback	Health professionals	
	Causes of shoulder pain and graphics were appropriate [PT/OS/OP]	OP, Female 40-49 yrs old – "I think the description is really quite good and that's the sort of language that I would usually use to describe what's happening as well."
	Patients	
	Clear explanation of the target population	Female 40-49 yrs old – "I like the way it breaks down the different types of shoulder pain within the broader subsection of subacromial shoulder pain."
	Helpful graphic of shoulder joint anatomy image	Male 30-39 yrs old – "I can understand it clearly, it helps having the picture there to be able to visualise it."
Improve clarity on the target population	Health professionals	
	Make the information more specific to a diagnosis [OS/PT]	OS, Male 40-49 yrs old – "We haven't even reached the stage where a diagnosis is made...shoulder pain is not a diagnosis."
	Differentiate between degeneration and traumatic rotator cuff tears [OS/OP]	OS, Male 40-49 yrs old – "Sometimes someone may develop inflammation...from an acute pinching of that bursa or the tendon. Or someone can have a traumatic event and actually tear their rotator cuff and it may resemble an impingement problem or they may be older patients and have chronic impingement pain, developing degenerative changes in the tendons in that region."
	Make the section more concise [GP]	GP, Female 30-39 yrs old – "There's a lot to look at and sometimes that can be overwhelming for some

		patients, I think they'll receive it but then maybe put it aside."
	Provide more detail on alternative diagnoses for shoulder pain [PT/OP/OS]	OS, Male 50-59 yrs old – "You certainly have covered some of the key things it can cause shoulder pain, but the other thing that's missing is that shoulder pain may come from elsewhere, for example cervicogenic pain."
	Patients	
	Make it clear the decision aid is for people with subacromial impingement syndrome (e.g. include the diagnosis in the title)	Male 30-39 yrs old – "Rotator cuff tears or impingement or bursitis should be the title, because that's really the patient demographic that you're looking at... Just 'shoulder pain' in general is a little bit vague at this point."
	Simplify 'subacromial shoulder pain' (e.g. 'shoulder pain')	Male 20-29 yrs old – "How necessary is it that you have subacromial in there? ... My first reaction was "oh wow, these are words that I don't understand, maybe this isn't for me.""
	Soften the exclusion criteria to avoid people with overlapping symptoms disregarding the decision aid	Female 40-49 yrs old – "One of the problems that I had is that frozen shoulder is not a very clear diagnosis and there could be overlap with subacromial shoulder pain. It [decision aid] might be still relevant to some people who have a potential diagnosis of frozen shoulder."
	Re-word or re-format this information	Female 40-49 yrs old – "'Do not read this form' is very clear but possibly, being in red, sounds quite alarmist."
	Health professionals	
Highlight that patients need to discuss this decision aid with a health professional	Emphasise that patients should discuss the decision aid with a health professional [OS/PT/GP]	OS, Female 50-59 yrs old – "The more information a patient has the better, I would love it if a patient came with something like this and said what do you reckon and then we could talk about their individual issue."
	Title needs to be revised [PT]	PT, Male 40-49 yrs old – "When you say at the top 'Shoulder pain should I have arthroscopic surgery?'

Why is that even a question? Why can't it be 'Shoulder pain', should I have a professional consultation?

	Health professionals	
	Information has a pathoanatomical focus that is inaccurate [PT/OS/CP]	CP, Male 20-29 yrs old – "It does make it sound very pathoanatomical which it can definitely be in a lot of cases but in that first description it almost seems like it's a couple of options that it could be, either rotator cuff tear or bursitis and there's definitely some other things to consider there."
	Information could drive patients towards surgery [CP/PT/OS]	PT, Male 20-29 yrs old – "So this first page if I were to be a patient looking at this I'd be like ok well this is clearly pointing me towards having surgery."
Revise the causes and symptoms of shoulder pain	Clarify that shoulder pain can be caused by overuse and work (e.g. heavy lifting) [GP/PT]	GP, Female 30-39 yrs old – "I find that most of the patients that I see that have it tend to be a middle aged group having used a lot of overhead repetitive activities."
	Re-format or re-word this information [PT/OS]	OS, Male 60-69 yrs old – "I know it's a lay term, the 'inflamed tendons' but 'degenerative rotator cuff tears' is often what we're dealing with."
	Patients	
	Describe what causes the structural issues associated with shoulder pain (e.g. explain why a tendon tears or a bursa gets inflamed)	Female 60-69 yrs old – "I suppose when somebody gets a sore shoulder you want to know, whether it's a swollen bursa, whether it's a tear, what's actually causing it?"
	Provide more information about potential aggravating activities (e.g. lifting overhead)	Male 20-29 yrs old – "Or even just 'your hands above your head' or something like that."
	Avoid jargon	Male 20-29 yrs old – "Non-medical folks are the people who haven't been seeing a doctor or YouTubing or Googling shoulder pain, are not going to be familiar with this."
Use positive messaging	Health professionals	

	Language will cause fear among patients [CP/PT]	CP, Male 20-29 yrs old – "There's a lot of very scary language in here too which is very nocebic; inflamed tendons, impingement, tears, swelling, fluid filled. Which for someone...see those things and think there's something very seriously wrong with me when there really very well might not be."
	Include positive messaging about prognosis and what pain means (e.g. pain doesn't equal damage, pain may get better with time, imaging findings are common in people without symptoms) [CP/PT/OP]	CP, Male 20-29 yrs old – "Having a line like that in there that most people with shoulder pain get better on their own with time - stay positive."
	Health professionals	
	Too much information [PT/CP/OS]	CP, Male 20-29 yrs old – "For the sake of just having a printout to give to somebody definitely the more visual and less words is probably good. I'm just thinking of it from a patient perspective where they want simplicity with direct answers."
Make this section more concise and relevant	Explanation of shoulder symptoms might be irrelevant for patients [GP/OS/PT]	PT, Female 30-39 yrs old – "I'm just wondering if the line of 'shoulder pain often makes it difficult to do simple everyday tasks' really needs to be there, these people will know that."
	Graphic of pain distribution might be more useful than a graphic of the shoulder anatomy [OS/PT]	OS, Male 40-49 yrs old – "I think a surface-based picture showing a highlighted area of pain going down the lateral part of their arm may be more useful than an anatomical picture."
	Remove the word 'arthroscopic' from decision aid [OS]	OS, Male 40-49 yrs old – "There's still debate on what's the best surgery for certain things, like open or arthroscopic"
WHAT ARE THE TREATMENT OPTIONS COVERED IN THIS DECISION AID?		
Positive feedback	Health professionals	

Graphic of surgery, details about surgery, non-surgical options are appropriate [PT/CP/OS] PT, Male 40-49 yrs old – "The thing is with arthroscopic repair you'd never do it justice with any type of picture anyway, so any general picture there would be fine. It doesn't scare me away, it looks gentle, plus I've been in the OR anyway."

Important that rehabilitation following surgery is highlighted [PT/OP/OS] OP, Female 40-49 yrs old – "To talk about rehabilitation, I think it is really responsible and important."

Patients

Order of options, description of options, formatting of information on surgery, including 'wait and see' as an option are appropriate Male 20-29 yrs old – "I do think those non-surgical options are important, that first one 'wait to see if your pain goes away'. I read that and go yeah, every single time my pain has eventually gone away."

Important to emphasise the downsides of surgery (e.g. long rehabilitation, anaesthetic) Male 20-29 yrs old – "That's definitely also pretty clear. I think the 3 to 12 months rehabilitation bracket, that would kind of freak me out a bit to see that upper band there."

Graphic of surgery was helpful to understand it is an invasive procedure Male 30-39 yrs old – "I think that does a good job of showing what they're planning on doing and that it's not something simple."

Health professionals

Balance the amount of information between non-surgical and surgical options [CP/PT/OS/GP/OP] PT, Female 30-39 yrs old – "I would look at those two options and get there's all this information about surgery and under no surgery there's just a few words, surgery must be the more involved better option for me because it looks bigger."

More detail needed on rehabilitation after surgery [PT] PT, Male 40-49 yrs old – "It may be the same commitment or greater than conservative rehab, so you just have to be aware that it's not just fixed...now you have to follow this rehabilitation protocol."

Include more detail on non-surgical options and how to progress management

bmjopen-2021-054033-1 on 23 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

1 2 3 4 5 6	Need a flowchart of non-surgical options [PT]	PT, Female 30-39 yrs old – "Yeah maybe even a flow chart of some kind...Is it a new event? Yes. Was it a full rupture? Yes, so you have surgery."
7 8 9 10	Highlight how long patients should try different non-surgical options before surgery [GP/PT]	GP, Male 50-59 yrs old – "If they are younger, I won't let them wait for six months, if they're not better within 4 to 6 weeks I'm probably sending them off to a surgeon if they have a torn tendon."
11 12 13 14 15	More detail is needed on muscle strengthening programs [PT]	PT, Male 20-29 yrs old – "Maybe a greater emphasis on what the current evidence shows...that strengthening can make a difference and even time with doing the right things could improve it."
16 17 18 19 20	Include evidence for non-surgical options [PT/OS]	OS, Female 50-59 yrs old – "I think it's important for them to know that if they wait long enough it will probably settle on its own, and we know the studies support that."
21 22 23 24 25	Emphasise the need for shared decision making [CP]	CP, Male 20-29 yrs old – "It's always going to be a shared decision making process, it's always going to take into account the patients values and what their lifestyle is like, how much this is impairing them."
26	Patients	
27 28 29 30	Provide more non-surgical options	Female 50-59 yrs old – "There's not a lot of options...I think it's telling me in my particular case that it's inevitable that I would have to have surgery eventually."
31 32 33 34 35 36	Provide evidence for various non-surgical options (e.g. options listed in the decision aid, lifestyle change, TENS, ultrasound, hydrotherapy, massage, diet, acupuncture, Chinese herbs)	Female 60-69 yrs old – "This has taught me a lot about surgery, whether to get surgery or not, but it hasn't told me a lot about whether cortisone injections are better than not having cortisone injections or whether physio is better than having no physio."
37 38 39 40	Provide more information on activity restrictions and how to modify activities while in pain	Female 60-69 yrs old – "I would like to know if I need to do anything or if it's just going to take time regardless of what you do...Or whether you should

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

just continue doing everyday things like vacuuming and things like that even though it's a little bit painful."

Highlight whether delaying surgery or non-surgical treatment is harmful or not
Female 60-69 yrs old – "I'd read a lot about that, where they said if you wait too long its irreparable sort of thing, Dr Google again."

Provide more information on 'wait and see' (e.g. highlight that you can trial non-surgical options while you 'wait and see')
Male 30-39 yrs old – "I think 6 months is a long time to wait and deal with an issue without seeking advice."

Present information in a way that helps patients understand the importance of non-surgical options
Male 30-39 yrs old – "Is there a recommendation from the health board or something where it says 'non-surgical option is recommended?'"

Health professionals

Inappropriate to mention medication and injections as options [PT/CP]
PT, Male 40-49 yrs old – "Personally I balk at the steroid injection option because the evidence for that is so poor. There's reasonably strong emerging evidence that its adverse effects are pretty high."

Re-format or re-word information on non-surgical options [OS/PT]
PT, Female 30-39 yrs old – "Rather than saying 'see a doctor for a corticosteroid injection' I would say 'discuss the options of a corticosteroid injection with the doctor.'"

Change the non-surgical options presented

Label 'no surgery' as something more positive (e.g. conservative, exercise-based) [PT]
PT, Male 40-49 yrs old – "I wouldn't call it 'no surgery', I would call it either 'conservative', 'exercise'... 'physio exercise therapy', 'strengthening therapy'..."

Do not mention specific exercises in the decision aid [GP]
GP, Female 30-39 yrs old – "Generally [patients] won't do [exercise] if they didn't pay money [to see a physiotherapist], if they didn't invest time into it they're not going to take on board the advice as much."

Mention the benefits of ultrasound for diagnosis and guiding injections [GP]
GP, Female 60-69 yrs old – "The other thing would be usefulness of ultrasound for the diagnosis...especially if you do ultrasound guided steroid injections."

bmjopen-2021-054033 on 130 August 2021 at 11:30 AM by guest. Protected by copyright.

1		
2		
3		
4	Waiting 6 months might be too long for patients to do nothing	OP, Female 40-49 yrs old – "I think to wait six
5	[PT/OP]	months, which is really the implication of that first
6		one, would be a long time for people in pain."
7	Order of non-surgical options might be inappropriate [CP/PT]	CP, Male 20-29 yrs old – "The order of the bullet
8		points, I mean hopefully they're not in any sort of
9		order of priority, to go straight to anti-inflammatories,
10		I'm biased towards non-pharmacological first."
11		
12	Health professionals	
13	Include indications for each surgery (e.g. failed conservative	GP, Female 30-39 yrs old – "Maybe in the decision
14	management, severe pain, age, rotator cuff tear, impingement,	making tool just clearly outlining the reasons for why
15	elite sports participation, massive cuff tears) [GP/OS/CP/PT]	you'd then become a surgical candidate."
16	Highlight that imaging findings in isolation aren't indications	OS, Female 50-59 yrs old – "It's not relevant to me
17	for surgery [PT/OS]	what the imaging says, it's relevant what the patient's
18		symptoms and signs are."
19		
20	Important for patients to know which procedure they are most	OS, Male 40-49 yrs old – "That's what I say to a lot of
21	likely to receive as this could influence recovery and	my patients, obviously it's very much dependent on
22	rehabilitation needs [OS]	the diagnosis and the anatomy of what's going on."
23	Re-format or re-word indications for surgery [PT]	PT, Male 30-39 yrs old – "I guess putting option one
24		and two there kind of implies that they have to have
25		surgery afterwards."
26		
27	Highlight that surgery may improve symptoms or anatomy but	OS, Female 50-59 yrs old – "I say to them their rotator
28	not address the cause [PT/OS]	cuff has got a headache, the surgery can take the
29		hammer away but you will still have the headache and
30		that headache will take time to improve. Unless you do
31		the anti-inflammatories and the rehabilitation therapy
32		that headache won't go away even if you have
33		surgery."
34		
35	Patients	
36	Provide more detail on the indications for surgery (e.g.	Male 20-29 yrs old – "I wonder about in that first
37	worsening pain)	underlined sentence...if the above options don't work,
38		if you can't live with the pain, or something like the
39		
40		
41		
42		
43		
44		
45		
46		

Include indications for surgery

above options are not feasible, you can't rest because you have to work."

Health professionals

Make the uncertainty of options clear [PT/OS]

OS, Female 50-59 yrs old – "By 6 months 75% are much better than they were before surgery. But would they have been there without surgery as well? Don't know. I think it's a hard question and we all think as surgeons that our surgery does wonderful things, that's one of the downsides of talking to surgeons we'll say we're fantastic and everything works really well."

Present evidence of benefits or harms in this section

Mention the success rate of surgery and non-surgical options [GP/PT/OS]

OS, Male 60-69 yrs old – "When I'm talking about the things that will help them and then get onto surgery, but also talk to them about things a lot of people spend a lot of money on, there's no evidence that they work as well."

Emphasise the harms of surgery [PT/CP/GP]

CP, Male 20-29 yrs old – "A 1% chance of you potentially dying from the surgery when it's no better than anything else that's a big risk but it doesn't sound like a lot."

Health professionals

Provide more detail on rehabilitation (e.g. time frames, will determine success, can be performed at home) [PT/OS/GP]

GP, Female 30-39 yrs old – "Surgery by itself is useless, if you're going to go through surgery expect a lot of rehab and if you can't commit to the rehab you're better off not going through surgery."

Change information on surgery

Include more details about the procedures [PT/OP/OS]

PT, Male 40-49 yrs old – "You could even explain a little more about the surgery, I think it's even ok to say a little more."

Re-format or re-word information on surgery [PT/OS]

OS, Male 40-49 yrs old – "I think again there's too much writing having lines like 'pain you can't deal with' is pushing the patient...again it's too wordy, so you would just say 'surgery is an option.'"

bmjopen-2021-054032 on 30 August 2021 by guest. Protected by copyright.

For Peer Review

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

1
2
3 Include details on recovery, comparing surgery to non-
4 surgical options [PT/CP/OS]
5
6
7

PT, Male 20-29 yrs old – "One example recently I had a shoulder patient and they got surgery and regretted it. They were saying they didn't know how much they would go backwards and how long it would take and the restrictions."

8
9 **Patients**

10 Provide less information on surgery

Male 20-29 yrs old – "The two different procedures, I haven't been to a doctor or physio about this, these are big words. Am I one? Am I the other? I don't really know. Do I care? Is it important?"

11
12
13
14 Provide more information on surgery and rehabilitation

Female 40-49 yrs old – "Perhaps an explanation of what rehabilitation means, I'm not sure I would really know what that means."

15
16
17
18 **Health professionals**

19 Modify the presentation of the two surgical options [GP]

GP, Female 30-39 yrs old – "I wonder in the surgery part, the box that has subacromial decompression and rotator cuff repair, if it would be easier to just have it listed as two hot points instead of two separate columns."

20
21
22
23
24 List non-surgical options first [PT/CP/OS]

OS, Male 40-49 yrs old – "Usually when we're talking about treatment...we're mentioning no surgery first. I think therefore that should be put first instead of having surgery first because it doesn't make sense to talk about surgery first when I'm seeing a patient."

25
26
27
28 **Modify the formatting or**
29 **graphics**
30

31 **Patients**

32 Improve the graphics (e.g. current image makes it appear
33 surgery is less invasive than it is, current image of surgery too
34 graphic, remove clock image, put image of person doing
35 exercise on the left so it stands out more)

Female 50-59 yrs old – "You might want to fine tune that one picture...is there another one you can put that's not so harsh?"

36
37 Improve the formatting of surgical options (e.g. list
38 procedures side by side, highlight procedures in a different
39 colour, put a clear dividing line or increase space between the
40

Male 20-29 yrs old – "Potentially on the first page you could have subacromial on the left and rotator cuff on the right to have continuity in that sense."

procedures, list surgical options before non-surgical options due to previous positive experience with surgery, replace '12 weeks' rehabilitation with '3 months' rehabilitation)

Re-word or re-format this section

Female 40-49 yrs old – "Again a small thing, the underlining probably needs to finish next to the full stop."

WHAT ARE THE LIKELY BENEFITS OF SURGERY COMPARED TO NON-SURGICAL OPTIONS?

Health professionals

Positive feedback

Icon array, statistics, footnotes and colour scheme are clear and appropriate [PT/CP/GP/OP]

OP, Female 40-49 yrs old – " I think the description is really quite good and that's the sort of language that I would usually use to describe what's happening as well."

Patients

Key messages box, bar graphs, icon array, description for certainty of evidence, explanation of placebo and formatting is appropriate

Female 60-69 yrs old – "I think the layout is good, when I read this it seemed simpler too."

Health professionals

Revise description for the certainty of evidence

Remove the description of the certainty of evidence [PT/OS]

OS, Male 40-49 yrs old – "So we're trying to teach patients how to interpret correct evidence and that is a hard thing to do."

Using green font for high-certainty evidence will drive patients towards surgery [PT/CP]

CP, Male 20-29 yrs old – "Some people might interpret the high certainty evidence as a better thing, but when you actually read it, subacromial decompression is little to no better than placebo."

Describe certainty of evidence as 'strong' instead of 'high-certainty' [PT]

PT, Male 40-49 yrs old – "I would drop the certainty and figure out another adjective or just 'strong' evidence, something like that, maybe a stronger word that's one word or two words. Low moderate is confusing."

Health professionals

bmjopen-2021-054032 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/> on December 2, 2021 by guest. Protected by copyright.

	Evidence doesn't match experience (e.g. careful patient selection will yield better outcomes) [OS/GP]	GP, Male 50-59 yrs old – "If you select the patient well enough often the result is not as bad as 3 percent, probably significantly higher."
	Evidence from Cochrane reviews may not be generalizable to patients [OS]	OS, Male 40-49 yrs old – "We don't really want to generalise the patient's condition because some patients may have pain that's caused by a specific problem that doesn't fit in with what these studies were looking at."
	Highlight that surgery may increase the speed of recovery or yield better long-term outcomes [OS]	OS, Female 50-59 yrs old – "I agree that at 12 months you're probably the same as if you didn't have surgery, but what's the patient journey in that 12 months between the two groups? That doesn't come out in this. So if the surgical group are sleeping and are back at work and are comfortable sooner then that's relevant."
Evidence doesn't match experience, more clarification needed	Acknowledge that statistics represent averages and individual results may vary [GP/OP]	OP, Female 40-49 yrs old – "[Suggested to write] 'Some patients report a better result than these statistics would show but plenty don't' ...or something like that."
	Add outcomes or provide further explanation for existing outcomes (e.g. include quality of life, define treatment success, emphasise pain results) [GP/PT/OP]	PT, Female 30-39 yrs old – "They fix what's inside and they might get range, but their pain is still ongoing and that was the reason they wanted the surgery in the first place."
	Mention the population and time points of the evidence [PT/CP/OS]	PT, Male 30-39 yrs old – "I know a lot of people would, especially in layman's terms, read this and say 'well that doesn't apply to me, I could heal better than that or it wouldn't affect me.'" It might be nice to put the patient population in these two studies just so people can say oh cool, it was mostly older people or mostly younger people. "
	Appears negative towards surgery but agrees the statistics are supported by evidence [PT/OS]	OS, Female 50-59 yrs old – "If they're cut and paste from a Cochrane review then that's the best evidence

that we've got so we can't dispute it, I just don't like it."

Highlight that surgery may be useful for preventing tears progressing even if there was no improvement in symptoms [OS]

OS, Male 40-49 yrs old – "In that group, a single tendon tear has become a one and a half to a two tendon tear, so the acute component which is just a tear has extended to involve the next adjacent tendons. I don't think that's covered well by any study."

Emphasise the uncertainty of the statistics [OS]

OS, Male 50-59 yrs old – "I think using 'somewhat confident' is an overstretch...the literature presents many unknowns...that's why there's a strong need for better studies."

Health professionals

Avoid numeric estimates (e.g. 3% could be framed as 'small') [PT]

PT, Female 30-39 yrs old – "I'd even take out the numbers and just have "on average surgery has less pain and better function but not by much" or something."

Replace bar graphs with a 'key messages' box [PT/CP]

CP, Male 20-29 yrs old – "I do like those boxes, I think that's probably even a little bit more helpful than the bar graphs themselves."

Choose one way to summarise the data (e.g. bar graph or key messages box but not both) [PT/OS]

PT, Male 40-49 yrs old – "I think as a patient you might lose somebody...a lot of numbers and words together and graphs, that's a lot, it's a busy slide or it's a busy section, and they're both together so it's a lot of information on both sides."

Repetition of evidence is biased against surgery [OS]

OS, Female 50-59 yrs old – "I think you need either the chart or the box or one of them, but all three to me is just repetition saying "don't have surgery", "don't have surgery", "don't have surgery.""

Statistics might be hard for patients to understand [PT/GP/OS]

GP, Female 30-39 yrs old – "I think they would expect that it's a yes or no answer, we know it or we don't."

Simplify the statistics

bmjopen-2021-054033 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/> by copyright.

bmjopen-2021-054033 on 30 October 2021 by guest. Protected by copyright.

Difference between surgeries might be hard for patients to understand [PT/CP]

PT, Male 20-29 yrs old – "Again it's like do they really know the difference between rotator cuff repair, subacromial decompression?"

Include the same comparison group when describing the evidence for both surgeries (e.g. remove placebo comparison) [PT/CP/OS]

CP, Male 20-29 yrs old – "I don't think people really understand the concept of placebo surgeries, that seems super weird to some people when I've told them about that... maybe just [say] "subacromial decompression doesn't seem to be better than some of the other options in terms of changes in pain and function.""

Re-word the certainty of evidence statement [PT]

PT, Male 30-39 yrs old – "I'm wondering if there's a different way to phrase that, we are very certain, that almost seems like it's an ad on a TV or something. I think that maybe "we are confident in these results as these were high quality studies" or something like that."

Patients

Provide information on the source of the evidence

Female 50-59 yrs old – "Then you get this percentage, I don't know how you got this percentage."

Provide more explanation about the certainty of evidence

Female 60-69 yrs old – "When you say this research on surgery is high quality, I wouldn't know what low quality is."

Provide more detail or revise the description of the evidence

Including both the 'key messages' box and icon array is confusing

Interviewer – "What about the percentage of people reporting treatment success in the four with the green and grey people?" [icon array for benefits that was removed]

Adding the age range of research participants is not necessary unless being outside this range would influence the benefits of surgery

Male 20-29 yrs old – "So is that coming out of a different set of research?"

Male 20-29 yrs old – "I'm 20. I'm not sure if there would be anything different on younger people. Even

		the ages of the participants, I'm not sure if that really changes it."
	Provide more detail on the non-surgical comparison groups	Female 40-49 yrs old – "I guess under subacromial decompression surgery you haven't given any alternatives to surgery, whereas under the rotator cuff repair you've given alternatives to surgery, so the injections, physiotherapy etc. Would those alternatives apply to both?"
	Clarify whether the evidence applies to those with severe pain	Male 20-29 yrs old – "I know it's very difficult to do, but if there was some table about scales of pain and severity of injuries, as to whether you should be going for surgery or non-surgery therapies."
	Patients	
	Clarify that numeric estimates are averages and that some people will experience better or worse outcomes	Male 30-39 yrs old – "I think that's important because I need to know what the average outcome is and then I can then speak to my GP or surgeon or someone to find out if my particular case is likely to be better than average or worse than average."
Contextualise the evidence to reflect uncertainty on an individual level	Emphasise that surgery may help but it will not be a cure	Male 40-49 yrs old – "It will help but it's not perfect. I guess that would probably be more relevant than stats about success"
	Statistics shouldn't influence treatment decisions as they are averages and patients should trust their health professional's advice	Male 40-49 yrs old – "The stats would not come into it for me at all. The stats are obviously for a large selection of the population, that's an average, it doesn't necessarily apply to my specific situation. So if it was determined by a health professional or medical professional that I needed surgery I'd just take it, the stats would not be a consideration whatsoever."
	Health professionals	
Modify the formatting or language used	Mention the findings before the certainty of evidence [CP]	CP, Male 20-29 yrs old – "So starting off with 'subacromial decompression is little to no better than

bmjopen-2021-054032 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

	placebo' and then following it up with there's high certainty evidence for this."
Shorten the 'key messages' box and include other information as footnotes [GP]	GP, Female 30-39 yrs old – "I like the version two where it's a smaller box there and it's cut out some of the text and put it below as well."
Make the bar graphs vertical [PT/CP]	CP, Male 20-29 yrs old – "I think that would make sense to a lot of people. Maybe even just going in a vertical sense might also help some folks but I don't think there's too much trouble with that."
Modify the colour scheme and presentation [PT]	PT, Female 40-49 yrs old – "I was just wondering if you could change the colour of different procedures so that they can see more difference."
Reduce the amount of text [PT/OS]	OS) Male 40-49 yrs old – "I think the second page, the likely benefit is just a bit wordy. I think a patient will get to that and just think, ugh, they will probably just be captured by the green men [icon array which was later remove]
Patients	
Shorten 'key messages' box and include other information as footnotes	Male 30-39 yrs old – "I think having a smaller box and just having these couple of points...makes it quicker to read to get the basic information and the important information."
Limit footnotes as they slow the reading pace	Male 30-39 yrs old – "Almost every single line you're going back down and then you're going back up. It's really not easy, it doesn't flow well and it's not easy to read that."
Suggested strategies to reduce text (e.g. not repeating information in each column, move some information to a 'further reading' section, replace words with graphics)	Male 20-29 yrs old – "A lot of text, I'm wondering if you could make it more infographic...I mean the boxes are good if you read it, but again I'm wondering if you can make it more easily digestible from a picture?"

	Distinguish between surgical complications, complications specific to the procedure (e.g. frozen shoulder) and poor outcomes [GP/OS/PT/OP]	OP, Female 40-49 yrs old – "Harm is different to unsuccessful outcomes so again, they have to be separated out."
	Mention revision surgery as a possible adverse event [OS]	OS, Male 40-49 yrs old – "So discussion about the need for re-do surgery is usually about poor healing... What I'm talking about there is failure of repair. There are other needs to do revision surgery when the repair has healed well but, for example, the patient may have a recalcitrant adhesive capsulitis or frozen shoulder."
Present minor and serious harms	Patients	
	Important to know both minor (e.g. loss of movement and strength) and serious harms	Male 30-39 yrs old – "Recovery time would be very important to me in a trade. Probably if there's other side effects as a possible loss of range of motion or strength because that would severely impact my work and day to day life."
	Definition of minor and serious adverse event is problematic because severity is subjective	Male 30-39 yrs old – "Saying a serious problem versus a non-serious problem, I think that's very relative to the patient because that becomes a material assessment."
Provide more context for harms	Health professionals	
	Presenting harms in a different section to 'benefits' doesn't give an understanding of harm vs. benefit [GP]	GP, Female 60-69 yrs old – "When you compare them [harms] to the benefits being very minimal, then the harms outweigh the benefits...the graphics don't really show that aspect."
	Compare the harms of surgery and non-surgical options [PT/CP]	CP, Male 20-29 yrs old – "One in one hundred people who are going through something like this, that's big. We look at rates of adverse reactions in manual therapies, you're looking at like 1 in 3 million."
	Patients	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Presenting harms in a different section to ‘benefits’ doesn’t give an understanding of harm vs. benefit

Interviewer: If it did get to a point where you needed to consider that [surgery], what would you most want to know while you’re weighing up that choice.

Male 30-39 yrs old – Probably the risks involved and the chance of success in comparison to that risk.

Emphasise surgery involves a general anaesthetic

Female 60-69 yrs old – "Again you’ve got to count into that anaesthetic, do I really want to go under anaesthetic for it as well?"

Health professionals

Harms might be overestimated [OS]

OS, Male 40-49 yrs old – "I would say deep infection in my practice, and having done arthroscopic surgery for more than 10 years, it might be 1 in 10,000. That doesn’t relate to me in my practice, so I wouldn’t give my patients those statistics."

Harms might be underestimated [PT]

PT, Female 30-39 yrs old – “My only other feedback is about the harms of arthroscopic surgery. I would look at that and think ...it’s not likely I’m going to be having any problems... 1 in 100 makes it look like it’s not that likely but actually 1 in 100 is quite high.”

Highlight populations who are at the greatest risk of harms (e.g. diabetes, other co-morbidities) [CP]

CP, Male 20-29 yrs old – "I know it takes up more space to add more information always, but letting them know or saying predisposing risk factors for serious problems or for frozen shoulder, comorbidity conditions, if any."

Health professionals

Format the harms section so it is consistent with the benefits section [PT]

OS, Male 40-49 yrs old – "Yeah, and present them in the same way. Whatever format you choose."

Move harms to practical issues section [CP]

CP, Male 20-29 yrs old – "So going back to what you were saying, what do we use for visuals, tables are probably really good. This [presenting harms in practical issues section] is just another way of showing

Evidence doesn't match experience, more clarification needed

Modify the formatting or language used

BMJ Open: first published as 10.1136/bmjopen-2021-054033 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/> on 19 December 2023 by guest. Protected by copyright.

the difference, this might even be another way when we're comparing the harms of arthroscopic surgery versus conservative care that might even be another way to compare the two so people can see."

Include in-text citations or state 'figures are from the most up to date medical research' [PT/CP]

CP, Male 20-29 yrs old – "To say that it's based on the most up to date medical evidence is probably really important."

Replace 'harm' with a less emotive word (e.g. 'risk', 'complication') [OS]

OS, Female 50-59 yrs old – "So this one I found even more emotive harm is in red and underlined... I wonder if there might be a different word, I know you're avoiding risks, you're using the word harms rather than risks, I don't know what other word might be better. "

Re-format to emphasise the harms (e.g. place minor harms on the left side of the page as they are most important, icon array downplays the true risk of harms)[PT]

PT, Male 20-29 yrs old – "Maybe with this graphic because the percentage is so small, it takes up a lot of space to do that. I guess it can be a good graphic to show how if you look at this you'd think I'd be pretty unlikely to get a problem is what you take away from that. The graphic does its job but if you think there's only half a person getting a serious problem that's probably not going to be me."

Patients

Change the terminology used (e.g. 'harms' too negative, change 'harms' to 'risk', change 'person' to 'people', define 'frozen shoulder')

Male 40-49 yrs old – "'Harms' seems dangerous. I suppose I think risk is inferred with those kinds of procedures. I'm just thinking there's maybe a better word than harm."

Change the formatting of numeric estimates (e.g. keep the same denominator for minor and serious adverse events, use 6 in 1000 rather than <1 in 100, use 4% instead of 4 in 100, remove icon array to save space, avoid text touching the boxes, seek help from a graphic designer)

Male 20-29 yrs old – "I don't know how much the picture does for me, if you just had a big 4% there that might get the same message across."

bmjopen-2021-054033, 2021, Downloaded from <http://bmjopen.bmj.com/> on December 17, 2022 by guest. Protected by copyright.

SUMMARY OF BENEFITS, HARMS, AND OTHER PRACTICAL ISSUES

Health professionals			
Positive feedback	The whole section is appropriate [GP/PT/OS/OP]	PT, Female 30-39 yrs old – "I like the idea of the table at the end about the practical issues that they should consider."	
	Being vague about costs is appropriate because as patients in the public system may not have any out-of-pocket costs [PT]	PT, Female 30-39 yrs old – "I feel like that's why so many people go surgically as opposed to going along a conservative physiotherapy driven pathway, because they've got to pay privately for physiotherapy and injections but they get their surgery done for free at the hospital and then will often go into the public system for their rehab as well."	
	Patients		
	Content, layout, and discussion about costs and recuperation after surgery is appropriate	Male 40-49 yrs old – "I'm looking at them through a different lens this time and I think they're pretty much spot on."	
	Global summary would be helpful for people without time to read the entire decision aid	Female 70-79 yrs old – "I think that it's very good. Some people who won't read through things. This is so neat and tidy and it takes you a minute or so to read."	
Health professionals			
Revise information on costs	Include the cost of non-surgical options (e.g. time, effort, cost without insurance coverage) [CP]	CP, Male 20-29 yrs old – "If this is just somebody paying out of pocket because they have shoulder pain it might actually be more expensive for them to seek care from a physio or a chiro than it would be to just go get a surgery because that's going to be covered through their insurance."	
	Be specific about costs to emphasis the true cost of surgery [PT/GP]	GP, Female 30-39 yrs old – "I think [include] the actual cost itself, which is very hard for you to put in a decision aid. I know depending on which area, which	

		surgeon, it could be very different, but just giving an idea of how much these costs are."
	Include costs related to time off work [OS/PT]	OS, Male 40-49 yrs old – "Out of pocket costs, correct, there's the other costs are not working, so if someone has used up their sick leave, whether it's surgery or no surgery, then they're on leave without pay so that's another cost to consider as well."
	Soften the language emphasising the costs of surgery [OS]	OS, Male 50-59 yrs old – "When you say the out of pocket costs for surgery are generally high, I think that's a value statement. I would say they are generally higher than non-operative treatment. Some surgeons don't charge anything, there's no out of pocket paying cost for some patients."
	Patients	
	Be more specific about costs (e.g. time off work, add "speak to your GP and insurance provider to understand exact costs", costs of non-surgical options, non-surgical options might equally expensive in some countries)	Male 70-79 yrs old – "How much is going to cost in the hospital? Am I covered by medical benefits? How much am I covered for my medical benefits? How long am I going to be in hospital? What are the charges?"
	Highlight that waiting times are long and costs are higher without private insurance	Male 30-39 yrs old – "What I want to do and other factors, financial factors as well and how long I have to wait for the sort of stuff, all these things."
	Health professionals	
Revise information on activity restrictions and post-surgical management	Revise timeframes for post-surgical activity restrictions [OS/PT]	OS, Male 50-59 yrs old – "Practical issues after decompression, I would suggest avoiding heavy lifting usually for six for twice that long, that's a bit short. They may elevate above their head at 1-3 weeks but we would not let them heavy lift for 6-8 weeks."
	Include timeframes for returning to normal function (e.g. sports, activities of daily living, pre-injury function) but also acknowledge the possibility patients won't return to normal [PT/CP]	PT, Male 30-39 yrs old – "I guess that's what people want to know - will I be able to play, pick up ball again."

1 2 3 4 5 6 7 8 9 10	Highlight that symptoms may improve, with or without surgery [GP]	GP, Female 30-39 yrs old – "No recuperation time frame, it makes it sound like with surgery you will just always have symptoms whereas without surgery you won't have symptoms. I understand that is correct, I'm trying to say, symptoms may come and go until rehabilitation is completed? I don't know how to word that."
11 12 13 14	Mention that people who do not have surgery will still have their usual symptoms and their improvement will depend on the success of the non-surgical options they try [OS]	OS, Female 50-59 yrs old – "If you don't have surgery there's no surgery to recuperate from, but you still have your primary symptoms, so you're not pain free."
15 16 17 18	Emphasise that symptoms will get worse following surgery due to the procedure [PT/OS]	PT, Male 30-39 yrs old – "It seems a lot of people don't fully conceptualise that, you can't even use the muscles in your shoulder for 6 weeks. That's a pretty big consideration."
19 20 21 22 23 24	Add a row for 'social support' (e.g. getting dressed, dishes, transport to appointments) [PT]	PT, Female 30-39 yrs old – "The other thing I would put in there is people getting to rehab if they don't have someone social support. Who's going to help them get dressed or do their dishes, take them to appointments."
25 26 27 28 29 30 31	Highlight that people must do exercises following surgery [PT/OS/CP]	OS, Male 40-49 yrs old – "I tell them that their shoulders will be stiff and will have deconditioned because they've been waiting for their tendons to heal and the structures to heal. It usually takes that extra 3 months of work to rehabilitate them enough that they can get back into manual labour type activities."
32 33 34	Define 'heavy lifting' [PT]	PT, Female 30-39 yrs old – "I think I'd try to be a little more specific with that, because heavy lifting is so specific to different people."
35 36 37 38 39 40 41 42 43 44 45 46	Include activity restriction timeframes for non-surgical options [PT]	PT, Male 30-39 yrs old – "Do you have anything in there for 'no surgery' as well, like most people do well in 6 weeks or expect 12 weeks?"

Highlight that recovery is influenced by the severity of a patients' pre-intervention symptoms [OS]

OS, Male 50-59 yrs old – "I think just recognising that there is a spectrum of severity of symptoms, that they're not all the same. Therefore, people with lower symptoms are generally more likely to improve."

Patients

Emphasise driving restrictions

Male 70-79 yrs old – "I would rather see 'you can't drive for 6 weeks' rather than 'you can.'"

Emphasise that patients may need treatment after surgery (e.g. physiotherapy, injections, exercise, etc.)

Male 40-49 yrs old – "I guess my experience is even after surgery there's still lots of injections, lots of medication..."

Highlight the need for patients to consider their individual circumstances before making any decisions (e.g. pain levels, social aspects, insurance, job demands, caring responsibilities, age, activity levels, sports participation, etc)

Male 40-49 yrs old – "I think that's probably a lot more important to consider with stats; where would you be without this if you can't go back to doing the things you want to do again? In another non-sporty point, if it affects a tradesman ability to earn income it affects their entire family's quality of life. So I think that's probably the more responsible point to make in it, rather than you'll get 9 or 6% less pain and that sort of stuff."

Add a column for 'no treatment'

Female 60-69 yrs old – "Are you allowed to have a column that says 'no treatment?'"

Health professionals

Separating practical issues by type of surgery results in too much information [PT]

PT, Male 20-29 yrs old – "Do they really know the difference between rotator cuff repair, subacromial decompression? I guess it's really only if they've been told that's what appropriate for them that they then go, which one are they?"

Split the practical issues section by type of surgery [GP]

GP, Female 30-39 yrs old – "Then the third page I guess the text looks like instead of lines we split something into two columns."

Discuss 'Follow-up with surgeon' in 'Recuperation' section [GP]

GP, Female 30-39 yrs old – "Maybe talk about the follow up in recuperation. I think that suits

Modify the formatting or language used

	recuperation more than it does procedure, in my train of thought anyway."
Could use a checkbox to reduce the number of words in the 'Activity restrictions' section (e.g. sling (tick); 3-4 weeks off work (tick), etc.) [CP]	CP, Male 20-29 yrs old – "If we were to reduce how many words are present, the row with all the activity restrictions and time off, it seems like that could be either a checkbox yes or no 'do you require a sling?'"
Include a summary of whole decision aid in the practical issues table in case people don't want to read the whole decision aid [CP]	CP, Male 20-29 yrs old – "That might be helpful if someone doesn't want to read three pages and they've just got one thing to glance at, we could direct them to just the one table."
Change title of this section to "What will my recovery look like after surgery and non-surgical options" to reduce bias against surgery [PT]	PT, Male 30-39 yrs old – "It's very heavily biased towards don't have surgery...Maybe instead of 'what practical issues should I consider' it might be better to have something along the lines of 'what would my recovery look like' or something like that, or 'what do these processes look like?'"
Remove this page entirely as patients will be losing interest by this point [OS]	OS, Male 40-49 yrs old – "I thought there shouldn't be a third page at all to be honest, by then the average punter is losing interest."
Patients	
Present practical considerations for the two types of surgery in separate columns to match the second page	Female 20-29 yrs old – [Shown two surgeries in separate columns as option #2] "I feel like I'm being super biased but I'm going to say the second one as well because that breaks down each surgery...[and] seems a little bit clearer."
Make the headings and sub-headings clearer	Male 20-29 yrs old – "So just in terms of the layout...I thought that was the subheading and the next chart or table was related to the what are the likely harms. So maybe a thicker bit in between might separate those ideas, just a bigger space or something like that."
Do not mention insurance as this is not relevant for people treated in the public system	Male 30-39 yrs old – "Just the first part where you say 'and insurance provider' I get a little bit offended there

bmjopen-2021-054033 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

anyway because it automatically presumes that I have private health insurance or that this is a work cover thing. It makes an assumption of the reader."

Acknowledge that timeframes are averages so patients don't get disheartened when they don't reach a milestone on time

Female 50-59 yrs old – "If you just say an average and you don't hit that 21-day average- unfortunately whatever affects your body affects your mind."

Change the colour of table to match other sections of the decision aid

Female 40-49 yrs old – "This table is quite clearly laid out...good use of shading and colour, although the blue is a different shade to what's used in the whole rest of the leaflet."

QUESTIONS TO CONSIDER WHEN TALKING WITH A HEALTH PROFESSIONAL

Health professionals

All questions are important [GP/PT/OS/OP]

OP, Female 40-49 yrs old – "I think that's really good because you can tick through that and make sure that they've understood the really important points."

Patients

Positive feedback

All questions are important

Male 20-29 yrs old – "Especially the last one [about] information and support. I think that's often one that I've seen some of my friends sometimes don't [ask]. So I think that's an amazing one to have in there."

Agrees that patients should be directed to ask questions

Female 20-29 yrs old – "I think they're good because when you're in an appointment setting for me I get really nervous and I don't always think."

Health professionals

Adding and removing questions

Add questions (e.g. "Do I understand what's wrong with my shoulder?"; "What level of activity can I get to if I have surgery versus not?"; "How much non-surgical management should I try before considering surgery?") [OP/PT/OS]

PT, Male 20-29 yrs old – "If I wait with my tear, is that going to mean it keeps tearing and then I need surgery later on and it gets worse?' that sort of thing."

Remove questions (e.g. "Do I know enough about my condition"; "Have I considered my individual circumstances") [OS]

OS, Male 40-49 yrs old – "I don't think that's a good question to ask because you're asking the health practitioner to read the patient's mind. 'Have I considered my specific situation?' Again, that's not something a health professional can answer in that format."

Patients

Add questions (e.g. "Can I have surgery later?"; "What is my diagnosis? Are there any other surgeries performed for this type of shoulder pain?"; "What other treatment options do I have/who else can I see?"; "How will my individual circumstances impact me?"; "What happens if I don't do anything?")

Male 20-29 yrs old – "Maybe add in there 'what is my diagnosis.'"

Health professionals

Increase the size of this section [PT/CP]

PT, Female 30-39 yrs old – "Can we make the 'other things that I can do 17 times bigger?' I almost think that box 'other things I can do' needs to be up there on that first page under no surgery."

Could replace "Questions to consider when talking with your doctor" section with "Any further questions, ask your doctor" to save space [GP]

GP, Female 30-39 yrs old – "If you needed to cut that out, I would cut out and say any 'further questions talk to your doctor.'"

Modify the formatting

Change the heading of this section so it applies to any health professional [PT]

PT, Male 20-29 yrs old – "Then the 'questions when talking to your doctor' are what we were saying before for your doctor or physio."

Change the heading of this section so it applies to GPs [PT]

Interviewer – "In which case do you think we need to direct people who to ask these questions to, rather than keeping it open like that? We've just said health professional, knowing that could be a whole number of people. Do you think we should say 'ask your GP', ask your physio or even just subcategories the questions depending on who they're asking."

bmjopen-2021-054033 on 30 August 2021. Downloaded from <http://bmjopen.bmj.com/>. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

PT, Male 40-49 yrs old – "Put great faith in GPs, they really care for their patients."

Patients

Remove this whole section to create space

Male 20-29 yrs old – "I don't think it adds a lot for me just because I think they're kind of obvious in a sense. I think questions would naturally arise from this."

Modify the formatting for the bullet points (e.g. words don't line up with the bullet points, too cramped, put questions in speech bubbles)

Female 40-49 yrs old – "In the third one, the spacing of the lettering is quite different to the spacing in the fourth one."

Change to "Questions to consider when talking with a health professional..." (instead of "your health professional")

Male 40-49 yrs old – "So when I just see the way that heading looks... I'm wondering if that's pointing them too specifically just to one person."

Combine the first two questions

Male 40-49 yrs old – "Am I clear about the benefits and the harms. That's the same as "Do I know enough about the benefits and harms?"

Categorise questions based on which health professional should answer them

Male 40-49 yrs old – "I'm wondering if there should just be more specifics around health professionals. I mean they're all health professionals, but some I've found to be more valuable than others."

ARE THERE OTHER THINGS I CAN DO?*

Patients

Positive feedback

"Other things I can do" box is great (1) [PT/CP]

PT, Male 40-49 yrs old – "So you make up for it by highlighting that which is cool, for saying the ongoing commitments. I like that you're putting that there."

Health professionals

Modify information to help people choose non-surgical options first

Move this section to the first page and make it clear surgery is a last resort [PT/CP]

CP, Male 20-29 yrs old – "Obviously really good advice, I think that should almost be at the forefront. These are pretty good options that they're probably going to have to try even before considering surgery because ...surgery is often a last resort."

Be specific about what exercises can be done [PT/CP]

PT, Male 20-29 yrs old – "I think in general you hit the broad spectrum of things, from a physical therapy standpoint obviously I might include beyond just strength and endurance exercises, strength, flexibility, endurance exercises."

Emphasise that there is often no need for early surgery and no harms in delaying surgery [OS/PT]

PT, Male 20-29 yrs old – "It was more a fear of 'if I don't do it now then what happens in the future?'"

OVERALL FEEDBACK

Health professionals

The graphics will assist non-English speaking people [PT/OS]

PT, Female 30-39 yrs old – "A lot of my clients don't speak English so I'll always go with pictures and graphics and really easy to understand things."

The decision aid will be an important tool for busy clinicians [PT/OS]

OS, Male 40-49 yrs old – "Assuming that the GPs have some musculoskeletal background and know a little bit about this problem...then having that information sheet [decision aid] certainly is helpful and I can assess the patient, they already know some of that information and I don't have to rehash everything."

Positive feedback

There is no information that is not important in this decision aid [PT/OS/GP]

PT, Male 30-39 yrs old – "Maybe you could take that's the problem it's all pretty useful."

Patients

Language, flow. explanations, content, length, and disclosure statement are appropriate

Male 30-39 yrs old – "That seems fairly straight forward as well, there doesn't seem to be anything in there that I don't either understand or isn't visually represented."

References are important but should be provided on request

Male 30-39 yrs old – "You could maybe just say 'references can be provided via emailing this address.' I don't know if you need to put all those references in there."

bmjopen-2021-054033, for review only. Do not use for clinical practice. Copyright.

The decision aid will be an important tool for patients who do not receive enough information in a consultation

Male 40-49 yrs old – "My surgeon, wonderful guy, really nice guy and he's done a great job, he never really explained a lot to me."

Health professionals

A 2-page decision aid is ideal [PT/CP/GP]

GP, Female 30-39 yrs old – "I don't know if this is possible, but I think two pages. So being able to... print it double sided and have just one piece of paper given to the patient it feels in my head less overwhelming than a bunch of paper being stapled together and saying here, read it all."

Reduce amount of information

The decision aid includes too much information [GP/OS/PT]

OS, Male 40-49 yrs old – "I thought it was a bit too busy...there's so much writing now I can't tell. If you're going to give that to the general public you've got to be like it's pretty straight forward."

Create a simplified version of the decision aid for patients [PT]

PT, Male 20-29 yrs old – "Maybe you give this one to the health practitioner and you do a separate for patients to take with them."

Remove some sections (e.g. questions to ask a health professional, references, rotator cuff repair surgery) [PT/OS]

PT, Male 30-39 yrs old – "Do the patients care specifically about references?"

Health professionals

Include a section on diagnostic imaging (X-Ray, MRI, Ultrasound) and the importance of not missing a serious disease [GP]

GP, Female 60-69 yrs old – "You don't want to miss arthritis or tumours or things like that. I think that would be useful to...understand the roles of each, of the x-ray ultrasound and MRI."

More detail needed

More detail is needed if the decision aid will be used without input from a health professional [PT]

PT, Male 20-29 yrs old – "I think the one that would be sent home you would want a little bit more detailed versus one that you are with a patient going over it."

Acknowledge who made this decision aid so patients can evaluate the quality of the information [OS]

OS, Male 50-59 yrs old – "Acknowledge what the background of the people constructing it is..."

Patients

Last page lacks a solution if a patient has tried everything

Male 20-29 yrs old – "I don't know if that exists or not but to give people a new solution."

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Encourage people to seek a second opinion or further information

Male 70-80 yrs old – "Do I have enough information and if not what do I do? I guess, if I answer that as no, I don't have enough information, then what do I do next, I've already spoken to the doctor."

Interviewer: That's a good point, maybe some links to further resources might be helpful.

Participant: Yeah."

Health professionals

Improve the colour scheme or layout (e.g. improve consistency, space out information) [GP/PT/OS]

PT, Male 40-49 yrs old – "I feel so critical, it's a bit gloomy."

Create separate decision aids for each procedure [CP/OS/GP]

OS, Female 50-59 yrs old – "It's too much covering decompression and rotator cuff repair on the one handout because they are two separate conditions and they're offered for different reasons and they should be separated."

Create separate decision aids for surgical and non-surgical options [GP]

GP, Female 60-69 yrs old – "Having surgery as a separate one [decision aid], because you wouldn't tell them about [surgery] straight away...I think it's too much information at the beginning, most people would get a bit alarmed if you talked about surgery at the beginning."

Create a video summary of the decision aid [PT/CP]

CP, Male 20-29 yrs old – "I feel like people nowadays don't have a great attention span...I almost wonder if somehow like a video, they could access it on Youtube or something free like that."

Include citations in the decision aid [CP]

CP, Male 20-29 yrs old – "I don't see a citation."

Acknowledge that treatment decisions might be influenced by the health professional the decision aid is discussed with [PT/OS]

OS, Female 50-59 yrs old – "In my experience, those who fail non-surgical do really well with surgery and so most of my patients do better, but I haven't got a

Formatting or distribution suggestions

	group to compare them to so I've got a very biased view of surgery because that's all I see."
Distribution suggestions for the decision aid (e.g. in a clinic, early in treatment, when a patient is considering surgery, after a diagnosis is made) [PT/OS]	OS, Male 40-49 yrs old – "The most useful thing that we're talking about surgery vs. no surgery, is at the junction when surgery is being considered and that is in the specialist's office, to me that would make the most sense."
Improve readability of the decision aid [PT/OS]	PT, Male 40-49 yrs old – "I think the challenge with language is, let's say your aim is to get the FKMG score of a reading literacy score down to year 8 or year 6. A message that details enough to be satisfactory for a consumer, but without getting there's a lot of words on this page."
Patients	
Include page numbers	Male 70-79 yrs old – "I kept looking for more pages, only because I thought it would have been a longer thing for no reason other than why won't it go page down anymore. So maybe 'page 1 of 3' or something like that on the top."
Create several decision aids (e.g. one for each surgery, one for patients and one for health professionals)	Male 30-39 yrs old – "It's like half of that is not relevant to me if I have subacromial decompression surgery and the other half is not relevant to me if I have a rotator cuff injury. It's like well give me the one that's relevant for me."
Improve readability (e.g. increase the font size, space out the text even if it means the decision aid is 3 pages, use a consistent design across pages, use a darker grey background)	Male 30-39 yrs old – "I think a lot of the text is too small...I know it's a draft, I just think it's a bit- it doesn't easily flow well."
Patients should read the decision aid before or after a consultation with a health professional so they don't waste a health professional's time and can ask questions	Male 30-39 yrs old – "You have to be able to ask questions to somebody, so a health professional it could be an GP, a physio, a nurse or a doctor...but probably not as a one-on-one, face-to-face thing. It

would be sitting in the waiting room, “read this, if you have any questions jot a little note, then when you come in ask the questions to clarify””

Remove 'disclosure' section

Male 30-39 yrs old – "That would then take out the whole funding thing as well... You declare that there's no conflict of interest or say nothing to disclose or nothing to declare."

Emphasise the question asking section and de-emphasise others (e.g. harms, causes of shoulder pain, references)

Male 40-49 yrs old – "Yeah, and maybe the very beginning one... “who should read this decision aid”, I think maybe that's too much. I think it's very doctor-y wordy... The very last one [questions section] I think is probably too little... [we need] a little bit of balance with the very last one and the very first one."

Move 'Important information' to above the references so patients are more likely to read it

Male 30-39 yrs old – "It blends in. As I'm coming down the page, if I saw it I would read that. Whereas it gets lost in references straight away."

Health professionals

Suspects bias or questions relevance of the decision aid

Thought the decision aid's underlying goal is to reduce the use of surgery and thought it should be more balanced [OS]

OS, Male 40-49 yrs old – "Really what you're trying to do is get them to not have the surgery."

Believes evidence is changing and the decision aid may become irrelevant overtime [OS]

OS, Male 40-49 yrs old – "I mean that's the current view, and in a year's time that might change."

Unsure of the applicability of the decision aid when patients don't have a diagnosis or when they have tried all the non-surgical options listed [OS]

OS, Male 40-49 yrs old – "The most useful thing that we're talking about, surgery vs no surgery, is at the junction where surgery is being considered and that is in the specialist's office. To me, that would make the most sense. Before that no one knows what's going on, no one's really talking about surgery, there might be hearsay and things like that, there might be guesses, but at that time you may not even have a diagnosis or imaging etc. Often when I see the patients they've already done a few of those conservative measures which have not worked, which is why they're in my

bmjopen-2021-054033 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

office...I guess if the decision aid is hitting them at the point where surgery vs no surgery, because there's not so much difference in the short to medium term, then it has to be done after the diagnosis is made I think, or surgery is being considered."

	Patients	
Decision aid swayed patients away from surgery	Swayed towards surgery because it might be beneficial (e.g. pain might get worse, small improvements in pain and function might be important for work, the risk of complications gets higher as you age, subacromial decompression might work if someone has tried all other options)	Female 50-59 yrs old – "It's not too bad for me to consider a shoulder surgery yet, but it's also making me think, maybe it's something I should have before it gets too bad."
	Swayed away from surgery (e.g. would only have surgery if it was a guaranteed solution as time off work and cost is a major inconvenience)	Female 40-49 yrs old – "To me you read that and think, I'm probably not going to go down that route."

CP: chiropractor; GP: general practitioner; PT: physiotherapist; OP: osteopath; OS: orthopaedic surgeon.

*: this section was removed from the decision aid to save space so we could provide more detail about non-surgical options on the first page.

Supplementary File 13. Reasons for not implementing feedback for each section of the decision aid.

Themes	Sub-themes	Reason for not implementing feedback
WHO SHOULD READ THIS DECISION AID?		
Improve clarity on the target population	Health professionals Make the information more specific to a diagnosis [OS/PT]	Identifying a structural nociceptive cause of subacromial impingement syndrome is not possible, so we decided to keep the diagnosis broad (i.e. subacromial impingement syndrome)
	Patients Make it clear the decision aid is for people with subacromial impingement syndrome (e.g. include the diagnosis in the title)	Opposing feedback to remove the term 'subacromial impingement syndrome'
Revise the causes and symptoms of shoulder pain	Health professionals Clarify that shoulder pain can be caused by overuse and work (e.g. heavy lifting) [GP/PT]	Potential causes of shoulder pain were removed as they were too speculative
	Patients Describe what causes the structural issues associated with shoulder pain (e.g. explain why a tendon tears or a bursa gets inflamed)	This information would have been too speculative due to a lack of evidence on this issue
Use positive messaging	Health professionals Language will cause fear among patients [CP/PT]	Opposing positive feedback from patients on our explanation of shoulder pain
	Include positive messaging about prognosis and what pain means (e.g. pain doesn't equal damage, pain may get better with time, imaging findings are common in people without symptoms) [CP/PT/OP]	Beyond the scope of this decision aid
Make this section more concise and relevant	Health professionals Explanation of shoulder symptoms might be irrelevant for patients [GP/OS/PT]	Opposing positive feedback on our explanation of shoulder symptoms
	Graphic of pain distribution might be more useful than a graphic of the shoulder anatomy [OS/PT]	Opposing positive feedback on our graphic of shoulder anatomy

WHAT ARE THE TREATMENT OPTIONS COVERED IN THIS DECISION AID?

	Health professionals	
	Need a flowchart of non-surgical options [PT]	Opposing positive feedback on the layout of non-surgical options
	Highlight how long patients should try different non-surgical options before surgery [GP/PT]	There is no evidence to guide timeframes on trying various non-surgical options. This could depend on treatment success and patient preferences
	More detail is needed on muscle strengthening programs [PT]	Beyond the scope of this decision aid
	Include evidence for non-surgical options [PT/OS]	This decision aid was developed for people considering surgery. We only included one treatment decision (i.e. surgery vs. non-surgical options) and hence, the evidence for surgery compared to non-surgical options
Include more detail on non-surgical options and how to progress management	Patients	
	Provide more non-surgical options	Opposing positive feedback that our decision aid covers all potentially valuable options
	Provide evidence for various non-surgical options (e.g. options listed in the decision aid, lifestyle change, TENS, ultrasound, hydrotherapy, massage, diet, acupuncture, Chinese herbs)	This decision aid was developed for people considering surgery. We only included one treatment decision (i.e. surgery vs. non-surgical options) and hence, the evidence for surgery compared to non-surgical options
	Highlight whether delaying surgery or non-surgical treatment is harmful or not	There is not enough evidence to address this issue. We suggested patients ask a health professional the following question: "Can I have surgery later? If so, how long should I wait before considering surgery?"
	Provide more information on 'wait and see' (e.g. highlight that you can trial non-surgical options while you 'wait and see')	Opposing positive feedback on the description of non-surgical options
Change the non-surgical options presented	Health professionals	
	Inappropriate to mention medication and injections as options [PT/CP]	Cochrane reviews on treatments for subacromial pain syndrome show glucocorticoid injections are superior

		to placebo and provide similar effects to non-steroidal anti-inflammatory drugs (22) and physiotherapy-delivered treatments (e.g. exercise, manual therapy, electrotherapy) (23, 24)
	Mention the benefits of ultrasound for diagnosis and guiding injections [GP]	Beyond the scope of this decision aid
	Waiting 6 months might be too long for patients to do nothing [PT/OP]	Opposing positive feedback on the description of non-surgical options
	Order of non-surgical options might be inappropriate [CP/PT]	Opposing positive feedback on the order of non-surgical options
Include indications for surgery	Health professionals	
	Highlight that imaging findings in isolation aren't indications for surgery [PT/OS]	Peripheral to the main purpose of this decision aid
	Important for patients to know which procedure they are most likely to receive as this could influence recovery and rehabilitation needs [OS]	Too dependent on an individual's symptoms
	Highlight that surgery may improve symptoms or anatomy but not address the cause [PT/OS]	Adding this information might be considered biased against surgery as non-surgical options might also not address the cause of symptoms
Present evidence of benefits or harms in this section	Health professionals	
	Mention the success rate of surgery and non-surgical options [GP/PT/OS]	We only included data on pain and function from the two Cochrane reviews of shoulder surgery. Including findings from responder analyses would have conflicted with feedback to avoid repetition of statistics
	Emphasise the harms of surgery [PT/CP/GP]	Adding this information would be biased against surgery. The presentation of benefits and harms in decision aids need to be balanced
Change information on surgery	Patients	
	Provide less information on surgery	Opposing positive feedback on the level of detail about surgery

BMJ Open: first published as 10.1136/bmjopen-2021-025403 on 11 December 2021. Downloaded from <http://bmjopen.bmj.com/> on December 11, 2023 by guest. Protected by copyright.

bmjopen-2021-054033, 2021, 30, August, 2021. Downloaded from <http://bmjopen.bmj.com/> on December 21, 2023 by guest. Protected by copyright.

Provide more information on surgery and rehabilitation

Opposing positive feedback on the level of detail about surgery and rehabilitation

WHAT ARE THE LIKELY BENEFITS OF SURGERY COMPARED TO NON-SURGICAL OPTIONS?

Revise description for the certainty of evidence	<p>Health professionals Remove the description of the certainty of evidence [PT/OS]</p>	Opposing positive feedback for acknowledging the certainty of evidence
Evidence doesn't match experience, more clarification needed	<p>Health professionals Evidence doesn't match experience (e.g. careful patient selection will yield better outcomes) [OS/GP] Evidence from Cochrane reviews may not be generalizable to patients [OS] Highlight that surgery may increase the speed of recovery or yield better long-term outcomes [OS] Add outcomes or provide further explanation for existing outcomes (e.g. include quality of life, define treatment success, emphasise pain results) [GP/PT/OP] Highlight that surgery may be useful for preventing tears progressing even if there was no improvement in symptoms [OS]</p>	<p>We did not change the evidence presented because it is vital numeric estimates of benefits and harms in decision aids are based on the highest quality available evidence (15, 27) We limited outcomes to pain and function from the two Cochrane reviews of shoulder surgery to avoid repetition We limited the potential benefits of surgery to data presented in the two Cochrane reviews of shoulder surgery</p>
Simplify the statistics	<p>Health professionals Avoid numeric estimates (e.g. 3% could be framed as 'small') [PT]</p>	Opposing positive feedback on the presentation of numeric estimates
Provide more detail and clarify the evidence	<p>Patients Adding the age range of research participants is not necessary unless being outside this range would influence the benefits of surgery</p>	Opposing feedback to mention the population of the evidence
Contextualise the evidence to reflect uncertainty on an individual level	<p>Patients Statistics shouldn't influence treatment decisions as they are averages and patients should trust their health professional's advice</p>	We did not change the evidence presented because it is vital numeric estimates of benefits and harms in

decision aids are based on the highest quality available evidence (15,27)

Modify the formatting or language used	Health professionals Make the bar graphs vertical [PT/CP]	We removed the bar graphs due to negative feedback
WHAT ARE THE LIKELY HARMS OF SURGERY?		
Present minor and serious harms	Health professionals Mention revision surgery as a possible adverse event [OS]	Not a direct harm of surgery
	Patients Definition of minor and serious adverse event is problematic because severity is subjective	Opposing feedback to separate minor and serious harms
Provide more context for harms	Health professionals Compare the harms of surgery and non-surgical options [PT/CP]	Data on the potential harms of non-surgical options was not available
Evidence doesn't match experience, more clarification needed	Health professionals Harms might be overestimated [OS]	We did not change the evidence presented because it is vital numeric estimates of benefits and harms in decision aids are based on the highest quality available evidence (15,27)
	Harms might be underestimated [PT]	
Modify the formatting or language used	Health professionals Move harms to practical issues section [CP]	Opposing feedback to use the same format when presenting benefits and harm
	Patients Replace 'harm' with a less emotive word (e.g. 'risk', 'complication') [OS] Change the terminology used (e.g. 'harms' too negative, change 'harms' to 'risk', change 'person' to 'people', define 'frozen shoulder')	'Harm' is a more accurate term than 'risk' and is used more frequently in the decision aid literature 'Harm' is a more accurate term than 'risk' and is used more frequently in the decision aid literature
SUMMARY OF BENEFITS, HARMS, AND OTHER PRACTICAL ISSUES		
	Health professionals	

	Include the cost of non-surgical options (e.g. time, effort, cost without insurance coverage) [CP]	Costs vary too much to include an accurate figure
	Be specific about costs to emphasis the true cost of surgery [PT/GP]	
Revise information on costs	Patients	
	Be more specific about costs (e.g. time off work, add "speak to your GP and insurance provider to understand exact costs", costs of non-surgical options, non-surgical options might equally expensive in some countries)	Costs vary too much to include an accurate figure
	Highlight that waiting times are long and costs are higher without private insurance	This might not apply to all health systems
	Health professionals	
Revise information on activity restrictions and post-surgical management	Add a row for 'social support' (e.g. getting dressed, dishes, transport to appointments) [PT]	Information mostly covered already
	Include activity restriction timeframes for non-surgical options [PT]	Activity restriction timeframes varied by health professional too much
	Highlight that recovery is influenced by the severity of a patients' pre-intervention symptoms [OS]	Suggestion was not relevant to this section
	Patients	
	Emphasise driving restrictions	Driving restriction timeframes varied by health professionals too much
Modify the formatting or language used	Add a column for 'no treatment'	'No treatment' is covered in the 'non-surgical options' column
	Health professionals	
	Separating practical issues by type of surgery resulted in too much information [PT]	Opposing feedback to separate practical issues by type of surgery
	Split the practical issues section by type of surgery [GP]	
	Could use a checkbox to reduce the number of words in the 'Activity restrictions' section (e.g. sling (tick); 3-4 weeks off work (tick), etc.) [CP]	Opposing positive feedback on the layout of this section

	Change title of this section to "What will my recovery look like after surgery and non-surgical options" to reduce bias against surgery [PT]	We removed the headings to save space
	Remove this page entirely as patients will be losing interest by this point [OS]	Opposing positive feedback on this section
	Patients	
	Acknowledge that timeframes are averages so patients don't get disheartened when they don't reach a milestone on time	We included timeframe ranges to address this comment
QUESTIONS TO CONSIDER WHEN TALKING WITH A HEALTH PROFESSIONAL		
	Health professionals	
Adding and removing questions	Remove questions (e.g. "Do I know enough about my condition"; "Have I considered my individual circumstances") [OS]	Opposing positive feedback on these questions
	Health professionals	
	Could replace "Questions to consider when talking with your doctor" section with "Any further questions, ask your doctor" to save space [GP]	Opposing positive feedback on this section
Modify the formatting	Change the heading of this section so it applies to GPs [PT]	Opposing feedback to change the heading of this section so it applies to any health professional
	Patients	
	Remove this whole section to create space	Opposing positive feedback on this section
	Categorise questions based on which health professional should answer them	Too much overlap between health professionals who could answer each question
ARE THERE OTHER THINGS I CAN DO?*		
	Health professionals	
Modify information to help people choose non-surgical options first	Move this section to the first page and make it clear surgery is a last resort [PT/CP]	We thought it was important to present the options (and evidence) before patients reflect on questions they could ask a health professional
	Be specific about what exercises can be done [PT/CP]	Beyond the scope of this decision aid

Emphasise that there is often no need for early surgery and no harms in delaying surgery [OS/PT]

We suggested patients ask a health professional the following question: "Can I have surgery later? If so, how long should I wait before considering surgery?"

OVERALL FEEDBACK

	Health professionals	
Reduce amount of information	A 2-page decision aid is ideal [PT/CP/GP]	Opposing feedback that all information in the decision aid is important
	The decision aid includes too much information [GP/OS/PT]	
	Create a simplified version of the decision aid for patients [PT]	Positive feedback from patients that this decision aid is easy to understand
	Remove some sections (e.g. questions to ask a health professional, references, rotator cuff repair surgery) [PT/OS]	Opposing positive feedback on these sections
	Health professionals	
More detail needed	Include a section on diagnostic imaging (X-Ray, MRI, Ultrasound) and the importance of not missing a serious disease [GP]	Beyond the scope of this decision aid
	More detail is needed if the decision aid will be used without input from a health professional [PT]	Positive feedback from patients that this decision aid is easy to understand
	Patients	
	Last page lacks a solution if a patient has tried everything else	There is no evidence to address this complex issue
		Positive feedback that the decision aid covers all important information
	Health professionals	
Formatting or distribution suggestions	Create separate decision aids for each procedure [CP/OS/GP]	This would prevent patients using the decision aid before consulting with a surgeon as they would not know which surgery they are most likely to receive
	Create separate decision aids for surgical and non-surgical options [GP]	The evidence compares surgery to non-surgical options, so it is important these options are listed in the same decision aid
	Create a video summary of the decision aid [PT/CP]	This is a consideration for a future project

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Acknowledge that treatment decisions might be influenced by the health professional the decision aid is discussed with [PT/OS] We felt that this information would not add value to this decision aid

Patients

Include page numbers

Create several decision aids (e.g. one for each surgery, one for patients and one for health professionals) This would prevent patients using the decision aid before consulting with a surgeon as they would not know which surgery they are most likely to receive

Remove 'disclosure' section Opposing positive feedback on the this section

Emphasise the question asking section and de-emphasise others (e.g. harms, causes of shoulder pain, references) Opposing positive feedback on these sections

Health professionals

Suspects bias or questions relevance of the decision aid Thought the decision aid's underlying goal is to reduce the use of surgery and thought it should be more balanced [OS] Opposing positive feedback suggesting the presentation of options was balanced

Believes evidence is changing and the decision aid may become irrelevant overtime [OS] We plan to update the decision aid as new evidence emerges

CP: chiropractor; GP: general practitioner; PT: physiotherapist; OP: osteopath; OS: orthopaedic surgeon.

*: this section was removed from the decision aid to save space so we could provide more detail about non-surgical options on the first page.

bmjopen-2021-054033, first published from <http://bmjopen.bmj.com/> on December 12, 2023 by guest. Protected by copyright.

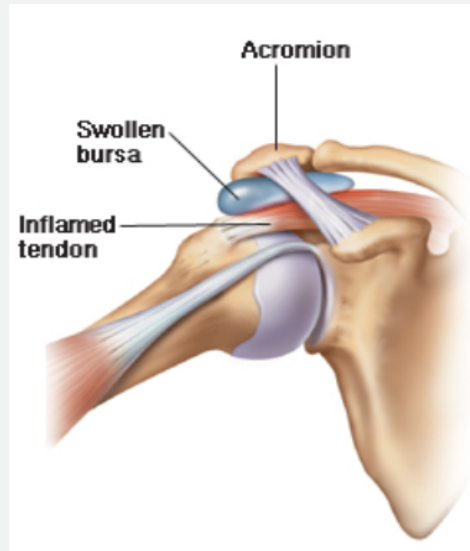
Shoulder pain: should I have arthroscopic surgery?

Is this decision aid relevant for me?

- This decision aid can help if you have shoulder pain due to common causes like rotator cuff tears or bursitis and are considering arthroscopic surgery of the shoulder

Cause and symptoms of shoulder pain

- **Shoulder pain** is commonly caused by rotator cuff tears, swelling of fluid filled sacs call bursa ('bursitis') or impingement.
- Impingement occurs due to contact between a bony part of the shoulder (the 'acromion') and the rotator cuff tendons or bursa (see picture). Contact usually occurs as you move your arm out to the side.
- Shoulder pain often makes it difficult to do simple everyday tasks like reaching into a high cupboard and washing hair.
- Symptoms often take time to settle and one half of patients are better by around 6 months.



SHOULDER PAIN: SHOULD I HAVE SURGERY?

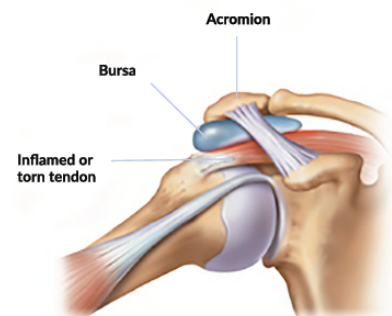
All information in this decision aid should be discussed with a health professional

+ Who should read this decision aid?

This decision aid is for people with persisting shoulder pain that is likely due to issues with rotator cuff tendons that move and support the shoulder (eg. inflammation, tears).

This type of pain often occurs around the shoulder. It makes it difficult to do simple tasks that involve lifting your arm above your head (eg. washing hair).

This decision aid does not apply to people who have other causes of shoulder pain like frozen shoulder (which causes pain and severe stiffness), osteoarthritis, or shoulder pain that begins after trauma immediately resulting in loss of movement or strength (eg. sudden rotator cuff tear, fracture, dislocation). If you're unsure of the cause of your pain, see a health professional.

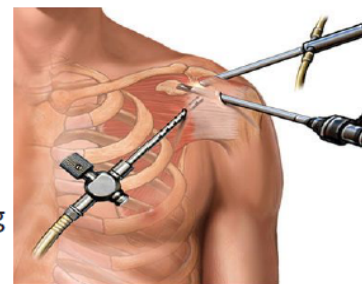


What are the treatment options covered in this decision aid?

1. Surgery ('subacromial decompression' and/or 'rotator cuff repair')

Surgery requires admission to hospital and an anaesthetic. The surgeon will make a small skin cut in your shoulder to perform the procedure. Your surgeon may perform one or both of the following procedures:

- **Subacromial decompression:** Increase the space under the acromion by either shaving back some bone, trimming some ligament or removing a bursa
- **Rotator cuff repair:** Reconnecting torn rotator cuff tendons



The surgeon may only decide on which procedure to perform while in surgery.

2. No surgery

You can choose to not have surgery and instead have injections, physiotherapy, medication or wait to see if it improves by itself.

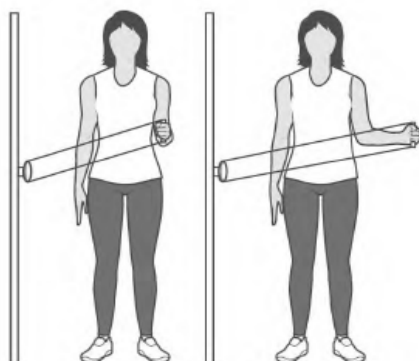


+ What are the treatment options covered in this decision aid?

NON-SURGICAL OPTIONS

Trying the following non-surgical options is recommended before considering surgery:

- Wait to see if your symptoms improve by themselves (roughly half of all people with these symptoms will recover within 6 months) and/or change your activities until the pain settles (eg. avoid carrying heavy grocery bags or take a break from sport if these activities cause pain)
- Take simple pain medicine (eg. paracetamol, anti-inflammatories)
- See a health professional (eg. physiotherapist) for advice on changing some daily activities and/or some muscle strength and endurance exercises
- See a health professional (eg. doctor) for a steroid injection



SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

You may consider surgery if the non-surgical options do not work and you can no longer put up with the pain. Typically surgery is not performed unless you have had symptoms for at least 3-6 months.

Surgery requires staying in hospital, having an anaesthetic and small skin cuts in your shoulder so the surgeon can perform one or both of the following:

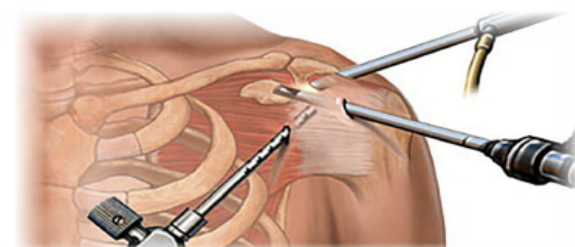
✓ Subacromial decompression surgery

Increase the space under the acromion by either shaving back some bone, trimming some ligament and/or removing a bursa

✓ Rotator cuff repair surgery

Reconnecting torn rotator cuff tendons

You will need to have rehabilitation involving exercises for at least 3 months following surgery. Much of this rehabilitation can be done at home.



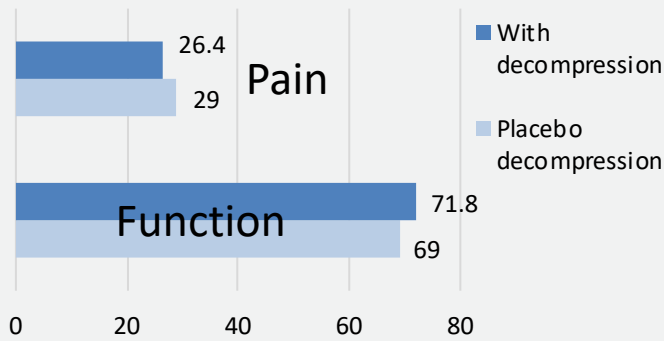
What are the likely benefits of arthroscopic surgery and non-surgical options?

Subacromial decompression vs. placebo

HIGH CERTAINTY EVIDENCE* that subacromial decompression is little-to-no better than placebo...

***We are very confident that the figures below represent the true benefits of surgery**

Placebo = the patient goes under anaesthetic and the surgeon inserts the surgical tools BUT no further procedure is performed



KEY MESSAGE: On average, surgery leads to **2.6% less pain** and **2.8% better function** compared to placebo surgery at 12 months.

Most patients would not consider these benefits important.

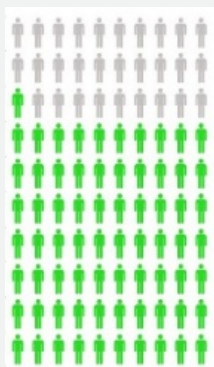
What % of people report treatment success?

treatment success rated by patients

treatment not a success

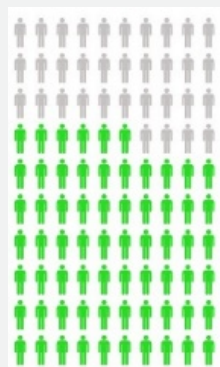
Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



71 out of 100 report success

Placebo



66 out of 100 report success

With surgery, **5 more people out of 100** will report their treatment as successful at 12 months.

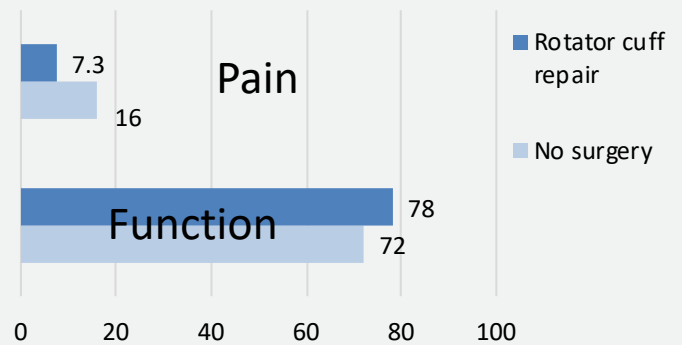
For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

Rotator cuff repair vs. no surgery

LOW-MODERATE CERTAINTY EVIDENCE* that rotator cuff repair is little-to-no better than no surgery...

***We have low-moderate confidence that the figures below represent the true benefits of surgery**

No surgery = injections, physiotherapy, medication or no treatment



KEY MESSAGE: On average, surgery leads to **8.7% less pain** and **6% better function** compared to no surgery at 12 months.

Most patients would not consider these benefits important.

What % of people report treatment success?

treatment success rated by patients

treatment not a success

Each figure represents one person. We can't predict whether you will be one of the people who is helped.

Surgery



95 out of 100 report success

No surgery



87 out of 100 report success

With surgery, **8 more people out of 100** will report their treatment as successful at 12 months.



+ What are the likely benefits of surgery compared to non-surgical options?

The figures on this page are based on the most up-to-date medical research as of 2020 (see references at the bottom of this page)

KEY MESSAGE

On average, patients report that surgery **improves pain and function by less than 10%** (ie. an improvement in pain or function of less than a 1 point on a 0-10 pain scale) compared to non-surgical options in the short term (6 months after) and longer term (1-2 years after) ^c. Because most patients do not notice these improvements, research concludes:

- Subacromial decompression surgery is not better than placebo or non-surgical options (ie. injections, exercise, medication or no treatment) for people with shoulder pain and no full-thickness rotator cuff tears ^a
- Rotator cuff repair surgery is little-to-no better than non-surgical options for people with full-thickness rotator cuff tears ^b

These results are averages. Surgery improves pain and function by more than 10% for some patients. But other patients have either **no improvements or worse** pain and function after surgery.

Further information:

^a For subacromial decompression surgery, we are very confident about this key message because research on this surgery is high-quality. This research was mostly conducted on people aged in their 40s, 50s and 60s, but is the best evidence we have for all ages.

^b For rotator cuff repair surgery, we are somewhat confident about this message because there is lack of high-quality research on this surgery. This research was mostly conducted on people aged in their 50s and 60s but is the best evidence we have for all ages. Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon.

^c Research suggests exercise or activities that you can do yourself at home may be just as helpful as a supervised exercise program.

What are the likely harms of arthroscopic surgery?

Each figure represents one person. We can't predict whether you will be one of the people who is harmed.

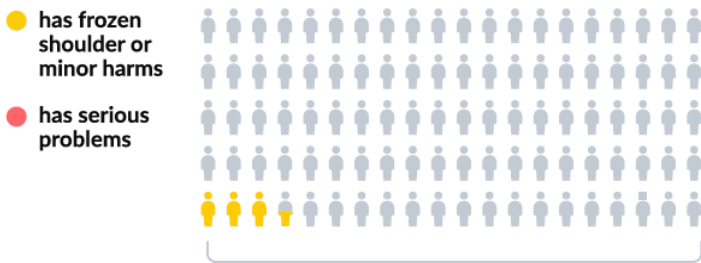


Based on moderate-certainty evidence, **less than 1 person per 100** that receives arthroscopic surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, deep vein thrombosis, pulmonary embolism, heart attack, stroke and pneumonia.

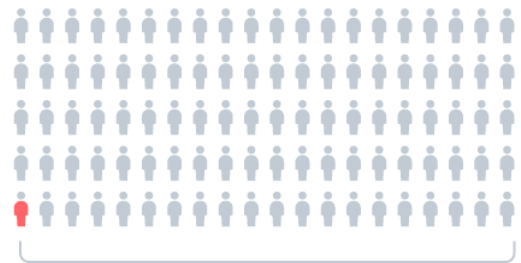


What are the likely harms of surgery?

Think of each figure as **1 person**. We can't predict if you will be one of the people who is harmed. Harms are more common among people with other health conditions (e.g. diabetes, heart disease).



About 3 people per 100 that have surgery will develop frozen shoulder (which may cause shoulder pain and stiffness for up to 2 years) or minor harms with surgery.

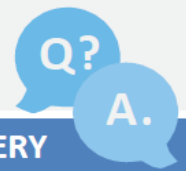


About 1 person per 100 that has surgery will have serious (and potentially life-threatening) problems like infection, nerve injury, heart attack, stroke and pneumonia.

only

What practical issues should I consider?

The table shows key practical issues for those who have arthroscopic surgery and those who do not.



	ARTHROSCOPIC SURGERY	NO SURGERY
Procedure and follow-up	Performed by a surgeon in an operating theatre. Requires an anesthetic. Individualised follow-up with wound care and exercise	Advice from a professional about other treatments may be useful (eg. injections, exercise, activity modification, medication)
Recuperation	You may use a sling a few days after surgery. Recuperation typically takes between 2-6 weeks	No recuperation needed
Activity restrictions	Avoid heavy lifting for 7-21 days, overhead activities for 6 weeks and pushing through your hands for 3 months	No activity restrictions
Time off work	Depends on recovery and demands of job. Usually a few weeks after surgery	No time off work
Driving	You can start driving as soon as you feel able to steer. This is normally after one week	No driving limitations
Costs	Out-of-pocket costs for surgery are generally high. There may also be out-of-pocket costs for physiotherapy after surgery	No surgical costs BUT there may be out-of-pocket costs for physiotherapy or injections



+ Summary of benefits, harms, and other practical issues

NON-SURGICAL OPTIONS

✓ Potential benefits

- May **improve by itself** (within 6 months half of people will recover) or with non-surgical options (ie. injections, exercise, or medication)
- **Avoid surgery**

− Potential harms

- May decide to **have surgery later**
- **Cost of non-surgical options** (eg. injection, physiotherapy)
- **Time to attend health appointments** (eg. for physiotherapy)
- Regardless of what treatment you have, your symptoms **may not improve**

SURGERY FOLLOWED BY 3-12 MONTHS REHABILITATION

✓ Potential benefits

- May provide **slight improvement in pain and function** compared to non-surgical options

− Potential harms

- Possible **surgical harms** (eg. frozen shoulder, infection)
- Your symptoms **may not improve** with surgery
- **Symptoms will temporarily be worse after surgery** due to the operation (eg. pain when sleeping or moving your arm)
- **Rehabilitation for 3-12 months** after surgery and time to attend rehabilitation
- May take up to **6 weeks** after subacromial decompression and **12 weeks** after rotator cuff repair to perform daily activities (eg. reach above your head, lift heavy objects)
- May take **3-4 months** after subacromial decompression and **6-12 months** after rotator cuff repair to return to heavy manual work, exercise, or sport
- **Out-of-pocket costs** are generally higher for surgery than non-surgical options. There may be **costs for rehabilitation** after surgery and due to **time needed off work**






Are there other things I can do?

- Strength and endurance exercises for your shoulder might help reduce pain and improve function.
- Modifying your activities and using pain relieving medicines when needed might help reduce pain.
- Seek advice from a health professional about the options that best suit your needs.
- Consider surgery at a later point if the above points do not help

Questions to consider when talking with your doctor...

- Do I need arthroscopic surgery?
- What happens if I don't have arthroscopic surgery?
- Do I know enough about the benefits and harms of:
 - » having arthroscopic surgery of the shoulder?
 - » not having arthroscopic surgery?
- Am I clear about which benefits and harms matter most to me?
- Do I have enough information and support to decide?

+ Questions to consider when talking with a health professional...

-  Do I need surgery? What happens if I don't have surgery? What happens if I do nothing?
-  Is surgery suitable for me? Which surgery is suitable for my diagnosis?
-  Can I have surgery later? If so, how long should I wait before considering surgery?
-  Have I considered my situation before making any decisions (eg. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport, etc)?
-  Do I understand enough about my condition and the benefits and harms of having surgery and not having surgery?



Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Items	Guide questions/description	Location
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Line 158
Credentials	What were the researcher's credentials? e.g., PhD, MD	Line 158
Occupation	What was their occupation at the time of the study?	Line 158
Gender	Was the researcher male or female?	Line 158
Experience and training	What experience or training did the researcher have?	Line 157
Relationship established	Was a relationship established prior to study commencement?	Line 161
Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	Line 161
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic	Line 158
Methodological orientation and theory	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Line 182
Sampling	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Line 134
Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Line 124-134
Sample size	How many participants were in the study?	Line 206
Non-participation	How many people refused to participate or dropped out? Reasons?	Line 210
Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Line 156
Presence of non-participants	Was anyone else present besides the participants and researchers?	Line 158
Description of sample	What are the important characteristics of the sample? e.g., demographic data, date	Table 1
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplementary Files 5 and 6
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Line 209
Audio/visual recording	Did the research use audio or visual recording to collect the data?	Line 163
Field notes	Were field notes made during and/or after the interview or focus group?	Line 160
Duration	What was the duration of the interviews or focus group?	Line 157
Data saturation	Was data saturation discussed?	Line 194

1 2 3 4 5	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Line 165
6 7 8	Number of data coders	How many data coders coded the data?	Line 183
9 10 11	Description of the coding tree	Did authors provide a description of the coding tree?	Supplementary File 12
12 13 14	Derivation of themes	Were themes identified in advance or derived from the data?	Line 182
15 16 17	Software	What software, if applicable, was used to manage the data?	Line 187
18 19 20	Participants checking	Did participants provide feedback on the findings?	Line 208
21 22 23	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Supplementary File 12
24 25 26	Data and findings consistent	Was there consistency between the data presented and the findings?	Supplementary File 12 and 13
27 28 29	Clarity of major themes	Were major themes clearly presented in the findings?	Supplementary File 12
30 31 32	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Supplementary File 12 and 13