

## Joint replacement (primary): hip, knee and shoulder

**[S] Evidence review for outpatient  
rehabilitations after shoulder replacement**

*NICE guideline*

*Intervention evidence review*

*October 2019*

*Draft for Consultation*

*This evidence review was developed by the National Guideline  
Centre, hosted by the Royal College of Physicians*



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# 1 <sup>1</sup> **Outpatient rehabilitation after shoulder** <sup>2</sup> **replacement**

## 1.1 <sup>3</sup> **Review question: In adults who have undergone primary** <sup>4</sup> **elective shoulder replacement, what is the clinical and cost** <sup>5</sup> **effectiveness of supervised outpatient rehabilitation versus** <sup>6</sup> **self-directed outpatient rehabilitation?**

### 1.2 <sup>7</sup> **Introduction**

<sup>8</sup> People following shoulder replacement are discharged from hospital once they can safely  
<sup>9</sup> manage to walk and perform their required personal activities of daily living. These people  
<sup>10</sup> are usually restricted in a sling for between 3 to 6 weeks after surgery. There is no national  
<sup>11</sup> consensus on the post-operative rehabilitation for people following shoulder replacement  
<sup>12</sup> surgery and most patients are referred to outpatient physiotherapy. In these appointments,  
<sup>13</sup> people are provided with graded exercises or functional activities to gradually increase their  
<sup>14</sup> strength, range of motion and functional performance, with progression encouraged by  
<sup>15</sup> healthcare professionals in a supervised and individual way, dependant on when the surgeon  
<sup>16</sup> feels immobilisation in a sling is no longer required. The aim of this rehabilitation is to  
<sup>17</sup> address physical problems including muscle weakness, low endurance and reduced joint  
<sup>18</sup> range of motion, as well as rehabilitation to facilitate return to extended activities of daily  
<sup>19</sup> living such as paid or unpaid work, domestic activities and other leisure pursuits.

<sup>20</sup> There is current variability in the timing and duration of postoperative outpatient rehabilitation  
<sup>21</sup> people receive following shoulder replacement. This variability extends to whether people  
<sup>22</sup> receive rehabilitation immediately or several weeks after their surgery and whether this  
<sup>23</sup> should be self-directed or supervised.

<sup>24</sup> Given this variability in the UK, this review seeks to find out what the clinical and cost  
<sup>25</sup> effectiveness is of self-directed outpatient rehabilitation compared to supervised outpatient  
<sup>26</sup> rehabilitation for people following shoulder replacement.

### 1.3 <sup>27</sup> **PICO table**

<sup>28</sup> For full details, see the review protocol in appendix A.

<sup>29</sup> **Table 1: PICO characteristics of review question**

<b>Population</b>	Adults who have undergone primary shoulder joint replacement.
<b>Interventions</b>	<ul style="list-style-type: none"><li>• Group based supervised post-operative rehabilitation commencing from first post-operative follow-up appointment</li><li>• Individually supervised post-operative rehabilitation commencing from first post-operative follow-up appointment</li></ul>
<b>Comparison</b>	<ul style="list-style-type: none"><li>• Self-directed rehabilitation from first post-operative follow-up appointment</li></ul>
<b>Outcomes</b>	<b>Critical</b> <ul style="list-style-type: none"><li>• Quality of life within 6 to 24 months (continuous) for example EQ-5D, EQ-VAS.</li><li>• Patient Reported Outcome Measures (PROMs) within at 6 to 24 (continuous)</li><li>• Revision of joint replacement (time to event)</li><li>• Reoperation including dislocation within 24 months (dichotomous)</li></ul> <b>Important</b> <ul style="list-style-type: none"><li>• Hospital readmissions: within 90 days (dichotomous)</li></ul>

	<b>To be extracted when not included within a PROM:</b> <ul style="list-style-type: none"><li>• Function at 6 to 24 months (continuous)</li><li>• Pain within at 6 to 24 months (continuous)</li></ul>
<b>Study design</b>	Randomised controlled trials  If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.

## 1.4 1 Clinical evidence

### 1.4.1 2 Included studies

- 3 A search was conducted for randomised trials and observational studies comparing the  
4 effectiveness of supervised versus unsupervised post-operative rehabilitation in people who  
5 have undergone shoulder joint replacement surgery.
- 6 No studies were included in the evidence review
- 7 See also the study selection flow chart in appendix C, study evidence tables in appendix D,  
8 forest plots in appendix E and GRADE tables in appendix H.

### 1.4.2 9 Excluded studies

- 10 See the excluded studies list in appendix I.

### 1.4.3 1 Summary of clinical studies included in the evidence review

- 12 No clinical evidence was identified.
- 13
- 14



## 1.5 1 Economic evidence

### 1.5.1 2 Included studies

3 No relevant health economic studies were identified.

### 1.5.2 4 Excluded studies

5 No health economic studies that were relevant to this question were excluded due to  
6 assessment of limited applicability or methodological limitations.

7 See also the health economic study selection flow chart in appendix G.

### 1.5.3 8 Unit costs

9 Some potentially relevant unit costs are provided below to aid consideration of cost  
10 effectiveness.

11 **Table 2: Cost per hour of hospital based physiotherapist or occupational therapist,**  
12 **by band**

Band 4	Band 5	Band 6	Band 7	Band 8a	Band 8b
£32	£35	£46	£55	£66	£78

13 *Source PSSRU 'Unit costs of Health and Social Care 2018'<sup>2</sup>*

## 1.6 14 Evidence statements

### 1.6.1 15 Clinical evidence statements

16 No relevant clinical outcomes were identified for this evidence review

### 1.6.2 17 Health economic evidence statements

18 No relevant economic evaluations were identified.

## 1.7 19 The committee's discussion of the evidence

### 1.7.1 20 Interpreting the evidence

#### 1.7.1.1 21 The outcomes that matter most

22 The critical outcomes were quality of life (QoL), Patient Reported Outcome Measures  
23 (PROMs), revision of joint replacement, and reoperation including dislocation. The follow up  
24 time points of QoL and PROMs were within 6 to 24 months to pick up the longer-term effects  
25 of outpatient rehabilitation. Patient Reported Outcome Measures (PROMs), time until joint  
26 replacements were revised, depression and disability. PROMs measure health gain in people  
27 undergoing joint replacement. They vary in terms of content and can cover a range of clinical  
28 measures such as QoL, pain, stiffness, and function. The revision outcome was to pick up  
29 the longer-term benefits throughout the lifetime of the replaced joint. Reoperation including  
30 dislocation within 24 months reveals the shorter term effects that can be assigned to  
31 outpatient rehabilitation. Early reoperation in shoulder replacement can be due to prosthetic  
32 instability, infection, humeral problems, or glenoid loosening and can be influenced by  
33 rehabilitation practice.



1 The important outcome was hospital readmission within 90 days. It was agreed to utilise  
2 function or pain outcomes if they were reported and not included in a PROM.

3 No evidence was found for this question.

4

#### 1.7.1.2 5 The quality of the evidence

6 No studies were included in the evidence review.

7

#### 1.7.2 8 Benefits and harms

9 The committee spoke about outpatient rehabilitation standard care as it currently stands.  
10 This is supervised individual rehabilitation appointments in the hospital or in the community.  
11 The committee consensus was that this works well for people after shoulder replacement  
12 and should not be altered without evidence or a strong consensus. No recommendation was  
13 made because there was no data to support one in the clinical review and there was no  
14 consensus among the committee to change usual care.

15 A patient member of the committee stated that shoulder replacement surgery is different to  
16 hip and knee surgery in that it is easier not to push oneself after shoulder surgery. A person  
17 has become so used to an existence utilising only 1 arm that falling back into that pattern  
18 after surgery is very possible. Based on this assessment the committee did not feel it was  
19 suitable to extrapolate from the hip and knee outpatient rehabilitation studies to make a  
20 recommendation for all people have shoulder replacement surgery. . However the  
21 committee did agree there were certain consensus recommendations that could be made for  
22 the people who have had shoulder replacement surgery. Firstly if they receive self-directed  
23 rehabilitation and have a contact for further advice and support if they are having problems  
24 with the rehabilitation program. Secondly offering supervised group or individual outpatient  
25 rehabilitation for people who have difficulties managing activities of daily living or ongoing  
26 functional impairment. Many people who have shoulder replacement surgery will receive  
27 supervised rehabilitation as usual care but this provides a certainty of this in this population.  
28 Lastly a recommendation to consider individual outpatient rehabilitation for people with  
29 cognitive impairment again reaches out to a group of people who may well do better with  
30 supervised rehabilitation. In addition a research recommendation was made to address the  
31 clinical question posed by this evidence review, is supervised or self-directed rehabilitation  
32 more effective for people after shoulder joint replacement?

#### 1.7.3 3 Cost effectiveness and resource use

34 No published economic evidence was found. In the absence of any clinical evidence,  
35 modelling was not attempted. The unit costs of physiotherapist and occupational therapist  
36 time were presented to the committee.

37 Supervised rehabilitation would represent a substantial cost to the NHS in terms of  
38 therapists' time, particularly if this is provided on a one-to-one basis rather than as a group.  
39 There is no evidence to indicate whether this is a cost effective use of resources. The  
40 committee did not feel that it was appropriate to extrapolate a recommendation for the entire  
41 shoulder replacement population based on the evidence for outpatient hip and knee  
42 rehabilitation review.

43 The committee thought that current practice was unknown due to a lack of data, but likely to  
44 be varied. Most people are likely to receive either some form of supervised outpatient  
45 rehabilitation or self-directed rehabilitation. It is unlikely shoulder replacement patients will  
46 get group exercise as the numbers are likely to be small unless they may be putting the

1 patients into a general shoulder class. Where (or if) group classes do occur, they would  
2 probably receive this after some form of outpatient one-to-one time.

3 The committee agreed a consensus recommendation that everyone who is undertaking self-  
4 directed rehabilitation knows who to contact for advice and support. This recommendation  
5 will not have a large resource impact. The rest of the recommendations were for vulnerable  
6 sub-groups. Offering additional care for these sub-groups is the minimum duty of care as  
7 current practice, and therefore no additional resource impact is expected from these  
8 recommendations.

9

#### **1.7.40 Other factors the committee took into account**

11 The committee spoke about specifics of the surgery that mean a sling must be used for an  
12 extended period. This is due to repair of the muscle at the front of the socket. Therefore, the  
13 decision of the surgeon to undertake the repair then controls whether it is possible to have  
14 early shoulder mobility and then early mobilisation.

15

16

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- 7

# 1 Appendices

## 2 Appendix A: Review protocols

3 **Table 3: Review protocol: supervised outpatient rehabilitation versus self-directed outpatient rehabilitation after shoulder**  
 4 **replacement**

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Outpatient rehabilitation after shoulder replacement
2.	Review question	In adults who have undergone primary elective shoulder replacement, what is the clinical and cost effectiveness of supervised outpatient rehabilitation versus self-directed outpatient rehabilitation?
3.	Objective	Rehabilitation includes education, advice, functional exercises and muscle work to restore strength and joint mobility and to improve patients' functional capacity. This review seeks to find out whether it is more effective and cost-effective to have self-directed or supervised postoperative outpatient rehabilitation after surgery.
4.	Searches	<p>The following databases will be searched:                      Cochrane Central Register of Controlled Trials (CENTRAL)                      Cochrane Database of Systematic Reviews (CDSR)                      Embase                      MEDLINE</p> <p>Searches will be restricted by:                      English language                      Human studies                      Letters and comments are excluded.</p> <p>Other searches:                      Inclusion lists of relevant systematic reviews will be checked by the reviewer.</p> <p>The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant.</p> <p>The full search strategies will be published in the final review.</p>
5.	Condition or domain	Primary elective shoulder joint replacement surgery

ID	Field	Content
	being studied	
6.	Population	<p>Inclusion: Adults who have undergone primary shoulder joint replacement.</p> <p>Exclude studies including people meeting any of the following criteria: Adults having joint replacement as immediate treatment following fracture Adults having revision joint replacement. Adults having joint replacement as treatment for primary or secondary cancer affecting the bones.</p>
7.	Intervention/Exposure/T est	<p>Group based supervised post-operative rehabilitation commencing from first post-operative follow-up appointment Individually supervised post-operative rehabilitation commencing from first post-operative follow-up appointment</p>
8.	Comparator/Reference standard/Confounding factors	Self-directed rehabilitation from first post-operative follow-up appointment
9.	Types of study to be included	<p>Systematic reviews RCTs</p> <p>If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.</p>
10.	Other exclusion criteria	<p>Non-English language studies. Abstracts will be excluded as it is expected there will be sufficient full text published studies available.</p>
11.	Context	N/A
12.	Primary outcomes (critical outcomes)	<p>Quality of life within 6 to 24 months (continuous) for example EQ-5D, EQ-VAS. Patient Reported Outcome Measures (PROMs) within at 6 to 24 (continuous) Revision of joint replacement (time to event) Reoperation including dislocation within 24 months (dichotomous)</p>
13.	Secondary outcomes (important outcomes)	<p>Hospital readmissions: within 90 days (dichotomous)</p> <p>To be extracted when not included within an extracted PROM: Function at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) Pain at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous)</p>

ID	Field	Content
14.	Data extraction (selection and coding)	<p>EndNote will be used for reference management, sifting, citations and bibliographies. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened for inclusion.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed for eligibility in line with the criteria outlined above.</p> <p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>An in-house developed database; EviBase, will be used for data extraction. A standardised form is followed to extract data from studies (see Developing NICE guidelines: the manual section 6.4) and for undertaking assessment of study quality. Summary evidence tables will be produced including information on: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control interventions; study methodology' recruitment and missing data rates; outcomes and times of measurement; critical appraisal ratings.</p> <p>A second reviewer will quality assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary).</p>
15.	Risk of bias (quality) assessment	<p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed:</p> <p>Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS)</p> <p>Randomised Controlled Trial: Cochrane RoB (2.0)</p> <p>Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.</p>
16.	Strategy for data synthesis	<p>Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5) to combine the data given in all studies for each of the outcomes stated above. A fixed effect meta-analysis, with weighted mean differences for continuous outcomes and risk ratios for binary outcomes will be used, and 95% confidence intervals will be calculated for each outcome.</p> <p>Heterogeneity between the studies in effect measures will be assessed using the I<sup>2</sup> statistic and visually inspected. We will consider an I<sup>2</sup> value greater than 50% indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented using random-effects.</p> <p>GRADE pro will be used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome.</p>

ID	Field	Content														
		<p>If the population included in an individual study includes children aged under 12, it will be included if the majority of the population is aged over 12, and downgraded for indirectness if the overlap into those aged less than 12 is greater than 20%.</p> <p>Publication bias is tested for when there are more than 5 studies for an outcome. Other bias will only be taken into consideration in the quality assessment if it is apparent.</p> <p>Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome.</p> <p>If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.</p>														
17.	Analysis of sub-groups	<p>Site of joint replacement: knee, shoulder, hip                      Age: working age, above working age                      Appointments type: virtual, in person                      Grade /experience of team member undertaking review                      Implant rating: ODEP &lt;10a, ODEP ≥10aAge</p>														
18.	Type and method of review	<table border="1"> <tr> <td data-bbox="660 842 1361 887"><input checked="" type="checkbox"/></td> <td data-bbox="1361 842 2123 887">Intervention</td> </tr> <tr> <td data-bbox="660 887 1361 932"><input type="checkbox"/></td> <td data-bbox="1361 887 2123 932">Diagnostic</td> </tr> <tr> <td data-bbox="660 932 1361 976"><input type="checkbox"/></td> <td data-bbox="1361 932 2123 976">Prognostic</td> </tr> <tr> <td data-bbox="660 976 1361 1021"><input type="checkbox"/></td> <td data-bbox="1361 976 2123 1021">Qualitative</td> </tr> <tr> <td data-bbox="660 1021 1361 1066"><input type="checkbox"/></td> <td data-bbox="1361 1021 2123 1066">Epidemiologic</td> </tr> <tr> <td data-bbox="660 1066 1361 1110"><input type="checkbox"/></td> <td data-bbox="1361 1066 2123 1110">Service Delivery</td> </tr> <tr> <td data-bbox="660 1110 1361 1187"><input type="checkbox"/></td> <td data-bbox="1361 1110 2123 1187">Other (please specify)</td> </tr> </table>	<input checked="" type="checkbox"/>	Intervention	<input type="checkbox"/>	Diagnostic	<input type="checkbox"/>	Prognostic	<input type="checkbox"/>	Qualitative	<input type="checkbox"/>	Epidemiologic	<input type="checkbox"/>	Service Delivery	<input type="checkbox"/>	Other (please specify)
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<input type="checkbox"/>	Qualitative															
<input type="checkbox"/>	Epidemiologic															
<input type="checkbox"/>	Service Delivery															
<input type="checkbox"/>	Other (please specify)															
19.	Language	English														
20.	Country	England														
21.	Anticipated or actual start date	12/010/18														
22.	Anticipated completion date	20/03/20														



ID	Field	Content
23.	Stage of review at time of this submission	Review stage
		Preliminary searches
		Piloting of the study selection process
		Formal screening of search results against eligibility criteria
		Data extraction
		Risk of bias (quality) assessment
		Data analysis
24.	Named contact	<p>5a. Named contact National Guideline Centre</p> <p>5b Named contact e-mail</p> <p>5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre</p>
25.	Review team members	<p>From the National Guideline Centre:</p> <p>Carlos Sharpin [Guideline lead] Alex Allen [Senior Systematic Reviewer] Rafina Yarde [Systematic reviewer] Robert King [Health economist] Agnès Cuyàs [Information specialist] Eleanor Priestnall [Project Manager]</p>
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be

ID	Field	Content
		considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
29.	Other registration details	
30.	Reference/URL for published protocol	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Joint replacement surgery, arthroplasty, outpatient rehabilitation
33.	Details of existing review of same topic by same authors	N/A
34.	Current review status	<input checked="" type="checkbox"/> Ongoing
		<input type="checkbox"/> Completed but not published
		<input type="checkbox"/> Completed and published
		<input type="checkbox"/> Completed, published and being updated
		<input type="checkbox"/> Discontinued
35.	Additional information	N/A
36.	Details of final publication	www.nice.org.uk

1 **Table 4: Health economic review protocol**

<b>Review question</b>	<b>All questions – health economic evidence</b>
<b>Objectives</b>	To identify health economic studies relevant to any of the review questions.
<b>Search criteria</b>	<ul style="list-style-type: none"> <li>• Populations, interventions and comparators must be as specified in the clinical review protocol above.</li> <li>• Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis).</li> <li>• Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.)</li> <li>• Unpublished reports will not be considered unless submitted as part of a call for evidence.</li> <li>• Studies must be in English.</li> </ul>
<b>Search strategy</b>	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
<b>Review strategy</b>	<p>Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from low or middle-income countries (e.g. most non-OECD countries) or the USA will also be excluded.</p> <p>Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).<sup>9</sup></p> <p><b>Inclusion and exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• If a study is rated as both ‘Directly applicable’ and with ‘Minor limitations’ then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile.</li> <li>• If a study is rated as either ‘Not applicable’ or with ‘Very serious limitations’ then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile.</li> <li>• If a study is rated as ‘Partially applicable’, with ‘Potentially serious limitations’ or both then there is discretion over whether it should be included.</li> </ul> <p><b>Where there is discretion</b></p> <p>The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.</p> <p>The health economist will be guided by the following hierarchies.</p> <p><i>Setting:</i></p> <ul style="list-style-type: none"> <li>• UK NHS (most applicable).</li> <li>• OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).</li> <li>• OECD countries with predominantly private health insurance systems (for example,</li> </ul>

Switzerland).

- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

*Health economic study type:*

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

*Year of analysis:*

- The more recent the study, the more applicable it will be.
- Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as ‘Not applicable’.
- Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations.

*Quality and relevance of effectiveness data used in the health economic analysis:*

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

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## 1 Appendix B: Literature search strategies

2 The literature searches for this review are detailed below and complied with the methodology  
 3 outlined in Developing NICE guidelines: the manual.<sup>9</sup>

4 *For more detailed information, please see the Methodology Review.*

### B.1.5 Clinical search literature search strategy

6 Searches were constructed using a PICO framework where population (P) terms were  
 7 combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are  
 8 rarely used in search strategies for interventions as these concepts may not be well  
 9 described in title, abstract or indexes and therefore difficult to retrieve. Search filters were  
 10 applied to the searches where appropriate.

11 **Table 5: Database date parameters and filters used**

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
Embase (OVID)	1974 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 5 of 12 CENTRAL to 2019 Issue 5 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None

### 12 Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprothe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.

15.	13 not 14
16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	exp Rehabilitation/
26.	Rehabilitation Nursing/
27.	rehab*.ti,ab.
28.	(prehabilitat* or pre habilitat*).ti,ab.
29.	Early Ambulation/
30.	(early adj3 (ambulation or mobili*)).ti,ab.
31.	Physical Therapy Modalities/
32.	exp Exercise Therapy/ or Physical Conditioning, Human/ or Occupational Therapy/ or Recreation Therapy/ or Rehabilitation, Vocational/
33.	Motion Therapy, Continuous Passive/ or Muscle Stretching Exercises/ or Manipulation, Orthopedic/ or Resistance Training/
34.	((physical* or exercise* or motion or movement or occupational or recreation* or vocational) adj3 (therap* or condition*)).ti,ab.
35.	(manipulation or MUA).ti,ab.
36.	((standardi?ed or SE or continuous passive motion or CPM or slider board or SB or range of motion or ROM or resistance or weight bearing or equilibrium or flexibility or stretch*) adj2 (therap* or exercise*)).ti,ab.
37.	physiotherap*.ti,ab.
38.	Hydrotherapy/
39.	(hydrotherap* or aquatic physiotherap*).ti,ab.
40.	Transcutaneous Electric Nerve Stimulation/
41.	(electric* nerve stimulation or TENS).ti,ab.
42.	Patient Education as Topic/
43.	(patient* adj3 (education or information or advice)).ti,ab.
44.	or/25-43
45.	24 and 44
46.	randomized controlled trial.pt.
47.	controlled clinical trial.pt.
48.	randomi#ed.ti,ab.
49.	placebo.ab.
50.	randomly.ti,ab.
51.	Clinical Trials as topic.sh.
52.	trial.ti.
53.	or/46-52
54.	Meta-Analysis/
55.	exp Meta-Analysis as Topic/

56.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
57.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
58.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
59.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
60.	(search* adj4 literature).ab.
61.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
62.	cochrane.jw.
63.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
64.	or/54-63
65.	Epidemiologic studies/
66.	Observational study/
67.	exp Cohort studies/
68.	(cohort adj (study or studies or analys* or data)).ti,ab.
69.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
70.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
71.	Controlled Before-After Studies/
72.	Historically Controlled Study/
73.	Interrupted Time Series Analysis/
74.	(before adj2 after adj2 (study or studies or data)).ti,ab.
75.	or/65-74
76.	exp case control study/
77.	case control*.ti,ab.
78.	or/76-77
79.	75 or 78
80.	Cross-sectional studies/
81.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
82.	or/80-81
83.	75 or 82
84.	75 or 78 or 82
85.	45 and (53 or 64 or 84)

#### 1 Embase (Ovid) search terms

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/
2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.

10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/
19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	exp rehabilitation/
24.	rehabilitation nursing/
25.	rehab*.ti,ab.
26.	(prehabilitat* or pre habilitat*).ti,ab.
27.	*mobilization/
28.	(early adj3 (ambulation or mobili*)).ti,ab.
29.	*physiotherapy/ or *kinesiotherapy/ or *exercise/ or *occupational therapy/ or *recreational therapy/ or *vocational rehabilitation/
30.	*movement therapy/ or *stretching exercise/ or *orthopedic manipulation/ or *resistance training/
31.	((physical* or exercise* or motion or movement or occupational or recreation* or vocational) adj3 (therap* or condition*)).ti,ab.
32.	(manipulation or MUA).ti,ab.
33.	((standardi?ed or SE or continuous passive motion or CPM or slider board or SB or range of motion or ROM or resistance or weight bearing or equilibrium or flexibility or stretch*) adj2 (therap* or exercise*)).ti,ab.
34.	physiotherap*.ti,ab.
35.	hydrotherapy/
36.	(hydrotherap* or aquatic physiotherap*).ti,ab.
37.	transcutaneous electrical nerve stimulation/
38.	(electric* nerve stimulation or TENS).ti,ab.
39.	*patient education/
40.	(patient* adj3 (education or information or advice)).ti,ab.
41.	or/23-40
42.	22 and 41
43.	random*.ti,ab.
44.	factorial*.ti,ab.
45.	(crossover* or cross over*).ti,ab.
46.	((doubl* or singl*) adj blind*).ti,ab.
47.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
48.	crossover procedure/
49.	single blind procedure/
50.	randomized controlled trial/



51.	double blind procedure/
52.	or/43-51
53.	systematic review/
54.	meta-analysis/
55.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
56.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
57.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
58.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
59.	(search* adj4 literature).ab.
60.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
61.	cochrane.jw.
62.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
63.	or/53-62
64.	Clinical study/
65.	Observational study/
66.	family study/
67.	longitudinal study/
68.	retrospective study/
69.	prospective study/
70.	cohort analysis/
71.	follow-up/
72.	cohort*.ti,ab.
73.	71 and 72
74.	(cohort adj (study or studies or analys* or data)).ti,ab.
75.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
76.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
77.	(before adj2 after adj2 (study or studies or data)).ti,ab.
78.	or/64-70,73-77
79.	exp case control study/
80.	case control*.ti,ab.
81.	or/79-80
82.	78 or 81
83.	cross-sectional study/
84.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
85.	or/83-84
86.	78 or 85
87.	78 or 81 or 85
88.	42 and (52 or 63 or 87)

#### 1 Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Arthroplasty] this term only
#2.	MeSH descriptor: [Arthroplasty, Replacement] this term only

#3.	MeSH descriptor: [Arthroplasty, Replacement, Hip] this term only
#4.	MeSH descriptor: [Arthroplasty, Replacement, Knee] this term only
#5.	MeSH descriptor: [Arthroplasty, Replacement, Shoulder] this term only
#6.	MeSH descriptor: [Hemiarthroplasty] this term only
#7.	(or #1-#6)
#8.	MeSH descriptor: [Joint Prosthesis] this term only
#9.	MeSH descriptor: [Hip Prosthesis] this term only
#10.	MeSH descriptor: [Knee Prosthesis] this term only
#11.	MeSH descriptor: [Shoulder Prosthesis] this term only
#12.	(or #8-#11)
#13.	((joint* or knee* or shoulder* or hip*) near/5 (surger* or replace* or prosthe* or endoprothe* or implant* or artificial or arthroplast* or hemiarthroplast*)):ti,ab
#14.	(or #7, #12-#13)
#15.	MeSH descriptor: [Rehabilitation] explode all trees
#16.	MeSH descriptor: [Rehabilitation Nursing] explode all trees
#17.	rehab*:ti,ab
#18.	(prehabilitat* or pre habilitat*):ti,ab
#19.	MeSH descriptor: [Early Ambulation] this term only
#20.	(early near/3 (ambulation or mobili*)):ti,ab
#21.	MeSH descriptor: [Physical Therapy Modalities] this term only
#22.	MeSH descriptor: [Exercise Therapy] explode all trees
#23.	MeSH descriptor: [Physical Conditioning, Human] this term only
#24.	MeSH descriptor: [Occupational Therapy] this term only
#25.	MeSH descriptor: [Recreation Therapy] this term only
#26.	MeSH descriptor: [Rehabilitation, Vocational] this term only
#27.	MeSH descriptor: [Motion Therapy, Continuous Passive] this term only
#28.	MeSH descriptor: [Muscle Stretching Exercises] this term only
#29.	MeSH descriptor: [Manipulation, Orthopedic] this term only
#30.	MeSH descriptor: [Resistance Training] this term only
#31.	((physical* or exercise* or motion or movement or occupational or recreation* or vocational) near/3 (therap* or condition*)):ti,ab
#32.	(manipulation or MUA):ti,ab
#33.	((standardised or standardized or SE or continuous passive motion or CPM or slider board or SB or range of motion or ROM or resistance or weight bearing or equilibrium or flexibility or stretch*) near/2 (therap* or exercise*)):ti,ab
#34.	physiotherap*:ti,ab
#35.	MeSH descriptor: [Hydrotherapy] this term only
#36.	(hydrotherap* or aquatic physiotherap*):ti,ab
#37.	MeSH descriptor: [Transcutaneous Electric Nerve Stimulation] this term only
#38.	(electric* nerve stimulation or TENS):ti,ab
#39.	MeSH descriptor: [Patient Education as Topic] this term only
#40.	(patient* near/3 (education or information or advice)):ti,ab
#41.	(or #15-#40)
#42.	#14 and #41

## B.2.1 Health Economics literature search strategy

2 Health economic evidence was identified by conducting a broad search relating to the joint  
 3 replacement population in NHS Economic Evaluation Database (NHS EED – this ceased to  
 4 be updated after March 2015) and the Health Technology Assessment database (HTA) with  
 5 no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research  
 6 and Dissemination (CRD). Additional health economic searches were run in Medline and  
 7 Embase..

8 **Table 6: Database date parameters and filters used**

Database	Dates searched	Search filter used
Medline	2014 – 01 May 2019	Exclusions Health economics studies
Embase	2014 – 01 May 2019	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 01 May 2019 NHSEED - Inception to March 2015	None

### 9 Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language

25.	Economics/
26.	Value of life/
27.	exp "Costs and Cost Analysis"/
28.	exp Economics, Hospital/
29.	exp Economics, Medical/
30.	Economics, Nursing/
31.	Economics, Pharmaceutical/
32.	exp "Fees and Charges"/
33.	exp Budgets/
34.	budget*.ti,ab.
35.	cost*.ti.
36.	(economic* or pharmaco?economic*).ti.
37.	(price* or pricing*).ti,ab.
38.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
39.	(financ* or fee or fees).ti,ab.
40.	(value adj2 (money or monetary)).ti,ab.
41.	or/25-40
42.	24 and 41

#### 1 Embase (Ovid) search terms

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/
2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/
19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20

22.	limit 21 to English language
23.	health economics/
24.	exp economic evaluation/
25.	exp health care cost/
26.	exp fee/
27.	budget/
28.	funding/
29.	budget*.ti,ab.
30.	cost*.ti.
31.	(economic* or pharmaco?economic*).ti.
32.	(price* or pricing*).ti,ab.
33.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
34.	(financ* or fee or fees).ti,ab.
35.	(value adj2 (money or monetary)).ti,ab.
36.	or/23-35
37.	22 and 36

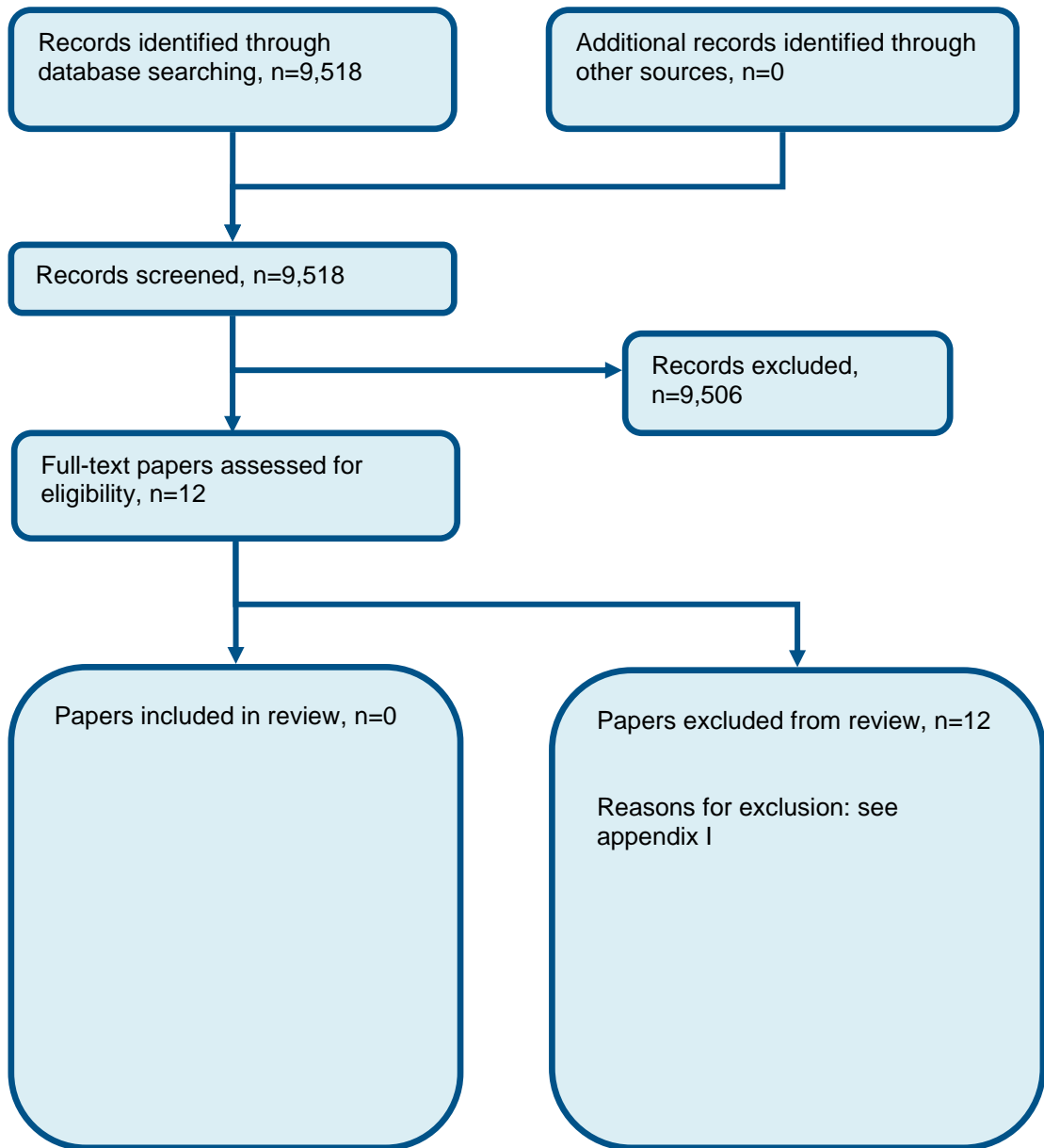
**1 NHS EED and HTA (CRD) search terms**

#1.	MeSH DESCRIPTOR arthroplasty
#2.	MeSH DESCRIPTOR arthroplasty, replacement
#3.	MeSH DESCRIPTOR arthroplasty, replacement, hip
#4.	MeSH DESCRIPTOR arthroplasty, replacement, knee
#5.	MeSH DESCRIPTOR arthroplasty, replacement, shoulder
#6.	MeSH DESCRIPTOR hemiarthroplasty
#7.	MeSH DESCRIPTOR joint prosthesis
#8.	MeSH DESCRIPTOR hip prosthesis
#9.	MeSH DESCRIPTOR knee prosthesis
#10.	MeSH DESCRIPTOR shoulder prosthesis
#11.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosth* or endoprosth* or implant* or artificial or arthroplast* or hemiarthroplast*))
#12.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN NHSEED
#13.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN HTA

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# 1 Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of outpatient shoulder rehabilitation



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# 1 **Appendix D: Clinical evidence tables**

2 No clinical evidence was found for this question.

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# 1 **Appendix E: Forest plots**

2 No clinical evidence was found for this question

3



1 **Appendix F: GRADE tables**

2 No clinical evidence was found for this question

3 **Appendix G: Health economic evidence tables**

4 No studies were found.

5

## 1 **Appendix H: Health economic analysis**

2 None.

## 3 **Appendix I: Excluded studies**

### I.1.4 **Excluded clinical studies**

5 **Table 7: Studies excluded from the clinical review**

Study	Exclusion reason
Christiansen 2016 <sup>1</sup>	Not review population
Hanchard 2014 <sup>3</sup>	Not review population
Holmgren 2012 <sup>4</sup>	Not review population
Keener 2014 <sup>5</sup>	Not review population
Lee 2012 <sup>6</sup>	Not review population
Litchfield 2013 <sup>7</sup>	Not review population
Mulieri 2010 <sup>8</sup>	Non-randomised study that did not control for confounding factors
Pastora-bernal 2017 <sup>10</sup>	Protocol for an RCT
Roddey 2002 <sup>11</sup>	Not review population
Salamh 2018 <sup>12</sup>	Not review population
Svendson 2014 <sup>13</sup>	Not review population
Wolf 1996 <sup>14</sup>	Conference abstract

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### I.2.7 **Excluded health economic studies**

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# 1 Appendix J: Research recommendation

## J.1.2 Postoperative outpatient shoulder replacement

3 **Research Question:** For people who have had primary elective shoulder replacement, does  
4 self-directed, supervised group or individual produce the most improvement in health-related  
5 quality of life in the first 2 years after surgery?

### 6 Why is this important:

7 People following shoulder replacement surgery should be provided with some form of  
8 rehabilitation post-operatively. However there remains uncertainty as to what this should be  
9 and how it should be delivered. It is important that healthcare professionals understand  
10 whether the interventions should be delivered face-to-face with the person, either in a group  
11 setting or one-to-one, or whether people are able to self-manage their rehabilitation after  
12 being provided with advice, education and guidance prior to hospital discharge. This is  
13 important as how well an individual rehabilitates following shoulder replacement surgery,  
14 irrespective of method used, may significantly impact on their overall outcome, particularly in  
15 respect to functional results. From a health service delivery perspective, this also has a  
16 significant impact on costs where a self-directed approach to rehabilitation has a lower cost  
17 to provide than requiring individuals to see a health care professional such as physiotherapist  
18 or occupational therapist, on a number of different occasions. Determining the clinical and  
19 cost-effective of one approach over another is therefore important.

20

### 21 Criteria for selecting high-priority research recommendations:

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<b>PICO question</b>	<p>Population: Adults who have undergone shoulder replacement surgery.</p> <p>Intervention(s): Post-operative rehabilitation provided prior to hospital discharge consisting of the following: exercise interventions, advice on pain management, advice and education on graded return to activities of daily living (ADLs) and extended ADLs and occupation, advice on progression of exercises and physical activity. To be delivered either individually or in a group-setting before hospital discharge.</p> <p>Comparison: Post-operative rehabilitation provided post-hospital discharge where the person is an out-patient. The intervention should consist of the following: exercise interventions performed in the presence of a healthcare professional to advice and guide exercise progression, advice on pain management, advice and education on graded return to activities of daily living (ADLs) and extended ADLs and occupation, advice on physical activity. To be delivered face-to-face during an out-patient appointment, either individually or in a group-setting.</p> <p>Outcome(s): Pain, function, health related quality of life, adverse events, health economic measures (direct and indirect costs), return to work</p>
<b>Study design</b>	Randomised controlled trial
<b>Other details</b>	Importance to patients or the population: rehabilitation is a key component to recovery following shoulder replacement surgery. Rehabilitation can impact on the early post-operative outcome of this population. There is geographical variability across the UK in what is provided in respect to rehabilitation for this population. Some individuals receive a self-directed approach where they are provided with exercises and advice prior to

hospital discharge and then progression is determined by the person. In other instances, people are referred to an out-patient appointment to receive physiotherapy and/or occupational therapy rehabilitation post-operatively. Determining what the superior approach to rehabilitation provision is for recovery is important to people to ensure that they receive the best rehabilitation interventions and advice to aid recovery and improve health related quality of life.

Relevance to NICE guidance: no suitable trials evidence post-operative rehabilitation for people following shoulder replacement was found. Furthermore, the current health inequality across the UK is a concern for NICE and it is hoped that this research recommendation may aid decision-makers to determine what best practice usual care is for people in the UK, to underpin future NICE recommendations.

Relevance to the NHS: improved post-operative rehabilitation outcomes could improve a person's health related quality of life and clinical outcomes. Improving these could reduce the risk of post-operative complications and prolonged rehabilitation needs. There is a difference in cost to provide self-directed compared to supervised rehabilitation. Therefore to ensure appropriate, evidence-based provision of resources effectively into front-line care, better understanding what rehabilitation approach should be taken is a research priority.

Feasibility: this trial is feasible in the current NHS as could be adopted into the healthcare pathway of this country's acute hospitals. However, challenges to undertake this trial may be around the provision of rehabilitation care which varies considerably. Therefore, for sites where usual care is self-directed, there may be challenges in gaining funding to provide up to six sessions of one-to-one physiotherapy after shoulder replacement surgery (for example). Managing excess treatment costs could therefore be a challenge when seeking financial support for such a trial.

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