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Management of frozen shoulder: a systematic review and cost-effectiveness analysis

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Appendix 4

Quality assessment checklist

Study quality assessment for RCTs and controlled trials	
1. Was the number of participants randomised stated?	1.1 Yes 1.2 No 1.3 Unclear 1.4 Not applicable (N/A)
2. Was the method of randomisation adequate (e.g. use of random number table, computer random number generator, coin tossing, shuffling of cards or envelopes, throwing of dice)?	2.1 Yes 2.2 No 2.3 Unclear 2.4 Not applicable (N/A)
3. Was allocation concealment adequate (e.g. central allocation, sequentially numbered opaque sealed envelopes)?	3.1 Yes 3.2 No 3.3 Unclear 3.4 Not applicable (N/A)
4. Were the treatment groups comparable at baseline for important prognostic factors?	4.1 Yes 4.2 No 4.3 Unclear 4.4 Not applicable (N/A)
5. Was a suitable statistical method used to adjust for possible baseline imbalance?	5.1 Yes 5.2 No 5.3 Unclear 5.4 Not applicable (N/A)
6. Was the study reported as being at least double blind?	6.1 Yes 6.2 No 6.3 Unclear 6.4 Not applicable (N/A)
7. Were patients blinded?	7.1 Yes 7.2 No 7.3 Unclear 7.4 Not applicable (N/A)
8. Were outcome assessors blinded?	8.1 Yes 8.2 No 8.3 Unclear 8.4 Not applicable (N/A)
9. Were caregivers blinded?	9.1 Yes 9.2 No 9.3 Unclear 9.4 Not applicable (N/A)
10. Was ITT analysis used (in the analysis, participants were kept in the intervention groups to which they were randomised, regardless of the intervention they received)?	10.1 Yes 10.2 No 10.3 Unclear 10.4 Not applicable (N/A)

11. Were there any unexpected imbalances in dropouts between groups?	11.1 Yes 11.2 No 11.3 Unclear 11.4 Not applicable (N/A)
12. If there were any unexpected imbalances in dropouts were they explained or adjusted for?	12.1 Yes 12.2 No 12.3 Unclear 12.4 Not applicable (N/A)
13. Was the study powered for at least one outcome?	13.1 Yes 13.2 No 13.3 Unclear 13.4 Not applicable (N/A)
Study quality assessment for case series	
14. Were selection/eligibility criteria adequately reported?	14.1 Yes 14.2 No 14.3 Unclear 14.4 Not applicable (N/A)
15. Was the selected population representative of that seen in normal practice?	15.1 Yes 15.2 No 15.3 Unclear 15.4 Not applicable (N/A)
16. Was an appropriate measure of variability reported?	16.1 Yes 16.2 No 16.3 Unclear 16.4 Not applicable (N/A)
17. Was loss to follow-up reported or explained?	17.1 Yes 17.2 No 17.3 Unclear 17.4 Not applicable (N/A)
18. Were at least 90% of those included at baseline followed up?	18.1 Yes 18.2 No 18.3 Unclear 18.4 Not applicable (N/A)
19. Were patients recruited prospectively	19.1 Yes 19.2 No 19.3 Unclear 19.4 Not applicable (N/A)
20. Were patient recruited consecutively?	20.1 Yes 20.2 No 20.3 Unclear 20.4 Not applicable (N/A)
21. Did the study report relevant prognostic factors?	21.1 Yes 21.2 No 21.3 Unclear 21.4 Not applicable (N/A)
22. Any other additional limitations?	22.1 Yes 22.2 No 22.3 Unclear 22.4 Not applicable (N/A)

Appendix 5

List of excluded studies

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
NCT00160784[128]							×[a]
NCT00840229[129]							×[a]
NCT00679887[130]	×						
NCT00261196[131]		×[b]					
NCT00873158[132]							×[a]
NCT01087229[133]		×					
NCT00884065[134]	×						
NCT00415441[135]	×						
NCT00742846[136]							×[a]
NCT00694538[137]	×						
NCT00680472[138]	×						
NCT00377624[139]	×						
NCT00211718[140]	×						
NCT00929305[141]	×						
NCT00172601[142]							×[a]
NCT00587626[143]	×						
NCT00163124[144]	×						
NCT00992927[145]							×[a]
NCT00875862[146]		×					
NCT01029600[147]							×[a]
Anonymous 1999[148]						×	
Anonymous 2000[149]							
Anonymous 2001[150]							
Anonymous 2004[151]	×						
Anonymous 2005[152]						×	
Anonymous 2005[153]						×	
Anonymous 2009[154]	×						
Ahmad 2009[155]					×		
Ahn 2008[156]					×		
Ainsworth 2007[157]	×						
Alegre Marcet 1959[158]	×						
Alexander 2010[159]					×		
Allano 2005[160]						×	
Altman 2005[161]	×						
Alvado 2001[26]					×[c]		
Andersen 1998[162]	×						
Andersen 1996[163]					×		
Andren 1965[164]					×		
Ankermann 1986[165]					×		
Aoki 1982[166]		×					
Aoki 1991[167]		×					

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Arias 1992[168]					×		
Arroll 2005[23]	×						
Arslan 2001[169]			×				
Atra 1986[170]		×					
Avetisova 1980[171]					×[d]		
Awad 1967[172]					×		
Azevedo 2008[173]		×					
Badalamente 2006[174]							×[e]
Badalamente 2009[175]		×[b]					
Bancheri 1993[176]					×		
Baslund 1991[177]						×	
Batra 1985[178]	×						
Battisti 2007[179]	×						
Battisti 2009[180]	×						
Baumann 1981[181]					×		
Baumgartner 1981[182]					×		
Baums 2007[183]					×		
Beaufils 1996[184]					×		
Beaufils 1999[185]	×						
Beckerman 1993[186]	×						
Bell 2003[187]					×		
Bellmann 1969[188]		×					
Bennett 2000[189]					×		
Beres 1979[190]					×		
Berger 1980[191]						×	
Berghs 2004[192]					×		
Berglezov 1986[193]					×		
Bergman 2002[194]	×						
Bergman 2004[195]	×						
Bergman 2005[196]	×						
Bergman 2010[197]	×						
Bergman 2010[121]	×						
Bertoft 1999[198]						×	
Bettermann 1982[199]	×						
Bicer 2005[200]	×						
Bierner 1989[201]						×	
Bilgici 2002[202]							×[f]
Bingol 2005[203]	×						
Biswas 1979[204]					×		
Blaine 2008[205]	×						
Blanchard 1999[206]	×						
Blauth 1989[207]						×	
Booi 1986[208]					×		
Bosch Olives 1967[209]	×						
Boyer 1994[210]	×						
Boylan 2005[211]						×	
Boylan 2005[212]						×	
Boyles 2005[213]					×		

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Bratanova 1978[214]						×	
Brigo 1981[215]					×		
Brox 2003[216]						×	
Buchbinder 2000[217]	×[g]						
Buchbinder 2003[218]					×		
Buchbinder 2004[219]		×					
Buchbinder 2004[220]						×	
Buchbinder 2006[221]	×[g]						
Buchbinder 2006[222]	×[g]						
Buchbinder 2006[223]					×		
Buchbinder 2007[224]	×[h]						
Buchbinder 2008[225]					×[c]		
Bulgen 1984[226]	×[h]						
Bumin 2001[227]	×[g]						
Bunker 1998[228]						×	
Calabro 1982[229]						×	
Caldwell 1986[230]	×[g]						
Callinan 2003[231]					×		
Camarinos 2009[232]							×[e]
Caniggia 1989[233]	×						
Capone 1994[234]	×						
Carette 2002[235]							×[i]
Carey 2008[236]	×						
Carter 2002[237]					×		
Casanova 1988[238]						×	
Castellarin 2004[239]	×						
Castelli 2006[240]	×						
Champion 2005[241]						×	
Chang 2009[242]	×						
Chavero Carrasco 2002[243]	×						
Chavez-Lopez 2009[244]	×						
Checchia 1991[245]	×[g]						
Chen 1985[246]					×		
Chen 1988[247]		×					
Chen 2002[248]					×		
Chen 2005[249]		×					
Chen 2006[250]	×[g]						
Chen 2006[251]			×				
Chen 2008[252]	×						
Chen 2009[253]	×						
Cheng 2008[254]		×					
Cherkashin 1969[255]					×[d]		
Cho 2005[256]	×						
Ciapetti 2006[257]	×						
Cinar 2010[258]					×		
Cleland 2002[25]					×[c]		
Cloke 2008[259]	×						

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Cohen 2000[260]	×[h]						
Compernolle 1987[261]					×		
Connolly 1972[262]						×	
Connolly 1998[263]						×	
Coombes 1984[264]						×	
Corazza 1982[265]		×[i]					
Corbeil 1992[266]	×						
Cossu 1993[267]	×						
Coudane 1988[268]				×			
Crawshaw 2009[269]	×						
Dacre 1987[270]							×[i]
Dahan 2000[271]		×					
Dal Conte 1990[272]	×						
Danneskiold-Samsoe 1996[273]						×	
De Bruijn 2007[118]	×						
de Jong 1991[4]	×						
de Jong 1998[274]	×[h]						
de la Serna 2004[275]	×						
de Macedo 2000[276]	×						
de Seze 1950[277]						×	
Debeyre 1971[278]						×	
Degen 1974[279]					×[d]		
Denicolai 1986[280]	×						
Desproges-Gotteron 1980[281]						×	
Devitt 2002[282]						×	
Deyle 1999[283]						×	
Dias 2005[5]						×	
DiMarcantonio 2006[284]						×	
Diwan 2005[285]					×		
Dodenhoff 2000[286]					×		
Dogru 2008[287]							×[k]
Dorian 1985[288]						×	
D'Orta 1985[289]	×[g,j]						
Drakos 2008[290]					×		
Duke 1981[291]		×					
Duschatko 2000[292]						×	
Echternach 1966[293]	×						
Ekelund 1992[294]		×[g]					
Elleuch 1994[295]					×		
Elleuch 2008[296]					×[m]		
Erlendsson 1996[297]						×	
Ernst 2004[298]						×	
Ernst 2009[299]						×	
Escalante Triay 1981[300]	×						
Esposito 1993[301]					×		

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Eulert 1981[302]					×		
Famaey 1984[303]		×					
Famaey 1982[304]	×						
Fan 2008[305]						×	
Fareed 1989[306]					×		
Farrell 2005[307]					×		
Feng 2003[308]				×			
Filshie 2005[309]						×	
Flannery 2007[310]					×		
Foster 2008[311]	×						
Fuhr 2005[312]						×	
Fujiwara 1993[313]					×[n]		
Fukuhara 1999[314]	×						
Fura 1981[315]	×						
Gabrhelik 2009[316]	×						
Gado 1996[317]	×						
Galarraga 2002[318]					×		
Galgano 2005[319]						×	
Garrido 2009[320]	×						
Gaspar 2009[321]					×		
Gavant 1994[322]					×		
Geraets 2004[323]	×						
Geraets 2005[324]	×						
Geraets 2006[120]	×						
Gerber 2001[325]	×						
Gilula 1978[326]	×						
Ginn 1995[327]	×						
Ginn 1997[328]	×						
Ginn 1999[329]						×	
Ginn 2001[330]	×						
Ginn 2004[331]	×						
Ginn 2005[332]	×						
Ginn 2009[333]	×						
Ginsberg 1991[334]	×						
Gobezie 2007[335]					×		
Goh 1997[336]	×						
Gotte 1986[337]		×					
Gotter 1987[338]		×					
Graber 1997[339]	×						
Grabovoi 1986[340]		×[b]					
Grammont 1982[341]					×		
Green 1998[29]					×		
Green 2003[342]					×[c]		
Green 2003[343]						×	
Green 2005[344]					×[c]		
Green 2006[345]					×		
Green 2010[346]							×[e]

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Grete 1981[347]						×	
Griggs 2000[348]					×		
Grossi 1986[349]	×						
Grubbs 1993[350]						×	
Gruehn 1965[351]						×	
Gu 1992[352]	×[g,o]						
Gudushauri 1975[353]	×						
Guerra de Hoyos 2004[354]	×						
Guler-Uysal 2004[355]					×[p]		
Guo 2006[356]						×	
Guo 2006[357]						×[o]	
Guo 2007[358]		×					
Gusarova 1989[359]						×[d]	
Gwilym 2007[360]						×	
Habib 2009[361]						×	
Haines 1982[362]	×[g]						
Hall 1988[363]						×	
Hall 2005[364]						×	
Hamdan 2003[365]					×		
Hamer 1976[366]					×		
Han 2006[367]					×		
Hando 2010[368]					×		
Hannafin 2000[369]						×	
Harryman 1993[370]						×	
Harryman 1997[371]					×		
Hart 1976[372]						×	
Hauzeur 2004[373]						×	
Hay 2001[374]	×						
Hay 2003[375]	×						
He 2000[376]					×[o]		
Heber 1983[377]						×	
Helbig 1983[378]						×	
Heller 2004[379]		×					
Hempel 1983[380]					×		
Herold 1982[381]						×	
Heuleu 1979[382]						×	
Hieber 1967[383]						×	
Ho 2009[384]					×		
Hoenle 1983[385]		×[b]					
Hollingworth 1983[386]	×						
Hollis 2006[387]	×[g]						
Hong 1982[388]	×						
Hormusjee 1980[389]	×						
Hossain 2008[390]	×						
Hosseini 2006[391]					×		
Hsu 1991[392]	×[g]						
Hu 1993[393]					×		

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Hu 2003[394]	×						
Hu 2004[395]					×		
Hu 2006[396]						×	
Huang 1996[397]					×		
Hulstyn 1993[398]						×	
Hummel-Berry 2001[399]	×						
Ibrahim 2006[400]					×		
Ide 2004[401]	×[g]						
Imai 1983[402]		×					
Indeck 1990[403]						×	
Ingram-Rice 2000[404]						×	
Itel 1988[405]						×	
Itzkowitch 1996[406]	×						
Ivanov 1986[407]					×[d]		
Jacchia 1968[408]					×		
Jacobs 1991[409]	×[g]						
Jacobs 1992[410]	×[g]						
Jacobs 2005[411]							×[l]
Jayson 1981[412]						×	
Jensen 1995[413]	×						
Ji 1988[414]						×	
Jia 1993[415]					×		
Jia 2008[416]				×[o]			
Jiang 1982[417]						×	
Jiang 1991[418]	×						
Jin 2003[419]					×		
Johnson 2007[420]					×[p]		
Jones 1997[421]			×				
Jones 1999[422]		×					
Joshi 1992[423]						×	
Judet 1985[424]					×		
Jurgel 2005[425]					×		
Kalke 1999[426]	×						
Kanai 2004[427]		×					
Kanai 2006[428]		×					
Kaptelin 1976[429]	×						
Karatas 2002[430]		×[b]					
Karkan 1985[431]					×[q]		
Katz 2000[432]	×						
Kay 1981[433]						×	
Kay 1990[434]					×		
Keilholz 1995[435]		×[b]					
Kent 1961[436]	×						
Kent 1985[437]	×						
Keyl 1982[438]					×		
Khan 2005[439]					×		
Khan 2009[440]					×		

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Khitrov 2007[441]		×[b]					
Kirillova 1986[442]					×		
Kivimaki 1996[443]	×[g]						
Kivimaki 2001[444]	×[g]						
Klinger 2002[445]					×		
Knebl 2002[446]	×						
Kneer 1983[447]					×		
Kneer 1994[448]	×						
Knusel 1984[449]	×[r]						
Koel 2008[450]						×	
Kong 2009[451]					×[c]		
Kostadinov 1980[452]	×						
Koubaa 2006[453]					×		
Kovacs 1982[454]	×						
Kucukdeveci 2005[455]	×						
Kuijpers 2006[456]	×						
Kulenkampff 1989[457]	×						
Kuptniratsaikul 2002[458]					×		
Kurtais Gursel 2004[459]	×						
Laidley 2004[460]						×	
Lanfranchi 1968[461]					×		
Laroche 1998[462]					×		
Laskowski 1985[463]					×		
LaStayo 1994[464]						×	
Latham 1989[465]						×	
Laznicky 1989[466]	×						
Lech 1993[467]	×						
Leclaire 1991[468]		×					
Lee 1973[469]	×[g]						
Lee 1974[470]	×[g]						
Lee 1986[471]						×	
Lee 2006[472]							×[f]
Lee 2009[473]					×		
Lee 2010[474]					×[c]		
Lehmann 1954[475]					×[s]		
Levenets 1982[476]					×		
Li 1984[477]	×[g]						
Li 2003[478]	×[g]						
Liang 1973[479]					×[s]		
Liao 2007[480]	×[o]						
Liaw 2000[481]					×[s]		
Lidstrom 1963[482]					×		
Liebolt 1970[483]						×	
Liem 2008[484]					×		
Liu 2003[485]		×					
Liu 2004[486]		×					
Lin 2005[487]					×[s]		
Lin 2009[488]		×					

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Livinya 1989[489]						×	
Long 1987[490]	×						
Lorbach 2010[491]			×				
Loyd 1983[492]					×		
Lu 1991[493]						×	
Lu 2008[494]			×[o]				
Ludwig 1998[495]						×	
Lundberg 1965[496]					×		
Luo 2005[497]					×		
Luziatelli 1984[498]		×					
Ma 2004[499]			×[o]				
Maiotti 2001[500]					×		
Maitland 1983[501]						×	
Mao 2003[502]			×[o]				
Marcus 1994[503]	×						
Mardjuadi 1978[504]	×						
Marx 2007[505]					×		
Massoud 2002[506]					×		
Mattara 1994[507]			×				
Mavrikakis 1991[508]	×						
Mayerhofer 1981[509]	×						
McClatchie 2009[510]	×						
McHardy 2008[511]					×[c]		
McKeever 1958[512]						×	
McQuay 1997[513]	×						
Meijer 2006[514]	×						
Melzer 1995[515]	×[g]						
Mencke 1988[516]	×						
Menkes 1990[517]		×					
Mert 2009[518]			×				
Meyer 1952[519]						×[t]	
Miccoli 1964[520]						×	
Michlovitz 2004[521]					×		
Miller 1991[522]						×	
Miller 2004[523]	×						
Miller 2009[524]	×						
Mior 2001[525]	×						
Miszczyk 2005[526]	×						
Mizuno 1976[527]						×	
Mohindra 1987[528]		×					
Molsberger 2010[529]	×						
Monreal González 2006[530]					×		
Montemagni 1989[531]						×[l]	
Moore 1976[532]	×						
Morgan 1995[533]		×					
Morris 1994[534]		×					
Moutounet 1984[535]	×						

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Mueller 1954[536]	×						
Mund-Hoym 1987[537]		×					
Munting 1978[538]	×						
Murnaghan 1955[539]					×[s]		
Musil 2009[540]					×		
Nabeta 2000[541]	×[n]						
Nabeta 2002[542]	×						
Naglic 2009[543]	×						
Naredo 2004[544]	×						
Narouze 2009[545]					×		
Nash 1989[546]					×[c]		
Neviaser 1991[547]						×	
Ng 2009[548]	×[g]						
Nicholson 1985[549]	×[h]						
Nicholson 2003[550]	×[h]						
Nicolova 1966[551]	×						
Nikolova 1970[552]					×		
Nobuhara 1990[553]	×[h]						
Noel 1997[554]						×	
Noskov 2005[555]		×					
Nouijai 2006[556]					×		
Nykanen 1995[557]	×						
Ogilvie-Harris 1995[558]	×[g]						
Ogilvie-Harris 1997[559]					×		
Ohshima 1987[560]						×[n]	
Ohta 2005[561]	×						
Okamura 1995[562]						×	
Olejarova 2004[563]						×	
Omari 2001[564]					×		
Orr 1997[565]						×	
Ortolani 1985[566]					×		
Othman 2002[567]					×		
Ou 1989[568]					×		
Ozaki 1989[569]					×		
Ozaki 1995[570]					×		
Ozaki 1996[571]					×		
Pages 1982[572]	×						
Pap 1998[573]					×		
Parker 1989[574]					×		
Parker 1989[575]						×	
Parsons 1967[576]					×		
Patel 1989[577]						×	
Patte 1983[578]						×	
Pearsall 1999[579]					×		
Peng 1987[580]	×						
Peng 2006[581]			×[o]				
Petri 1987[582]	×						
Petukhov 1979[583]						×[d]	

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Philadelphia Panel 2001[584]	×						
Piotte 2004[585]					×		
Pittler 2008[586]					×[c]		
Placzek 1998[587]					×		
Polimeni 2003[588]	×						
Politano 1982[589]					×		
Pollock 1994[590]					×		
Poonam 1990[591]	×[g]						
Qiu 2006[592]					×		
Quigley 1954[593]						×	
Quigley 1982[594]						×	
Quin 1965[595]					×[s]		
Quraishi 2006[596]							×[u]
Quraishi 2008[597]	×[g]						
Radaelli 1984[598]						×[j]	
Rainbow 2008[599]					×		
Ramsey 2009[600]						×	
Refior 1984[601]	×						
Reichmister 1999[602]					×		
Ren 2006[603]		×					
Rendeiro 2006[604]					×		
Revel 1999[605]						×	
Rey 1991[606]						×	
Rhind 1982[607]		×					
Rich 1985[608]						×	
Richardson 1975[609]	×						
Rigato 2002[610]	×						
Ritchie 1996[611]	×						
Ritzmann 1999[612]						×	
Rizk 1982[613]					×[s]		
Rizk 1983[614]					×[s]		
Rizk 1994[615]	×[h]						
Roberts 1965[616]	×						
Romoli 2000[617]	×						
Rompe 1981[618]						×	
Roques 1984[619]					×		
Roubal 1996[620]					×		
Rowlingson 1986[621]	×						
Saadat Niaki 2005[622]	×						
Saadeh 2005[623]	×						
Saeidian 2007[624]			×				
Saggini 1996[625]	×[h]						
Sakeni 2007[626]					×		
Sanders 1990[627]						×	
Sandor 2000[628]						×	
Sandor 2000[629]						×	
Santalena 1998[630]						×	

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Sauvain 1985[631]						×	
Scendoni 1987[632]						×	
Scheef 1979[633]						×	
Schieroni 1985[634]					×		
Schomacher 2007[635]						×	
Schultheis 2009[636]						×	
Schultze 2004[637]		×[b]					
Schulz 1986[638]						×	
Schwitalle 1998[639]		×					
Scott 2009[640]	×						
Segmuller 1995[641]					×		
Shah 2007[22]					×[c]		
Sharma 1993[642]					×[s]		
Sharma 2009[643]	×[h]						
Shchekotov 1977[644]					×		
Shchepina 1989[645]					×[d]		
Shehab 2000[646]	×						
Shiraishi 1991[647]	×						
Sileghem 1991[648]	×						
Simpson 2004[649]					×		
Singh 1980[650]					×		
Singh 2010[651]					×		
Skorogliadov 1990[652]		×					
Skorogliadov 1990[653]					×[d]		
Skoroglyadov 1986[654]						×[d]	
Slullitel 2000[655]							×[e]
Smidt 2005[656]						×	
Snow 2009[657]	×						
Sokk 2007[658]			×				
Spacca 2005[659]	×						
Speed 2004[660]					×		
Speed 2006[661]						×	
Spier 1984[662]						×	
Spresser 2002[663]						×	
Srivastava 1972[664]					×		
Srour 2008[665]	×[g]						
Stavnichii 1985[666]					×[d]		
Stavnichii 1986[667]					×[d]		
Steinbrocker 1974[668]					×		
Stoddard 1955[669]					×		
Stodell 1981[670]						×	
Stoker 1991[671]						×	
Stratz 2002[672]	×[b]						
Strobel 1996[673]	×						
Strunce 2009[674]	×						
Sun 1996[675]	×[g]						
Sun 2001[676]	×[g]						
Sun 2002[677]						×	

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Surenkok 2009[678]	×						
Swirski 1971[679]						×	
Taller 1985[680]		×					
Talybov 1981[681]					×[d]		
Talybov Yu 1981[682]		×[b]					
Tam 2010[683]	×[g]						
Tamai 1999[684]					×		
Tamai 2004[685]					×		
Tan 1995[686]						×	
Taskaynatan 2004[687]			×				
Taskaynatan 2005[688]	×						
Taverna 1990[689]	×[g,j]						
Teys 2008[690]	×						
Thakur 1991[691]						×	
Thomas 1981[692]	×						
Thumb 1987[693]		×					
Todorov 1972[694]					×[d]		
Toker 2008[695]	×						
Toplicanec 1986[696]							×[f]
Trehan 2010[697]					×		
Tripathi 1979[698]		×[b]					
Tsarin 1990[699]						×	
Tsukayama 2002[700]					×[c]		
Tsun-Nin 1977[701]	×						
Turner-Stokes 1996[702]						×	
Tuzlukov 1990[703]					×[d]		
Ucuncu 2009[704]	×						
Ueno 1995[705]					×		
Uhlemann 1991[706]	×						
Uhthoff 2002[707]						×	
Uitvlugt 1993[708]		×					
Ulmer 1982[709]	×[h]						
Vad 2003[710]					×		
Valtonen 1967[711]					×		
Valtonen 1974[712]	×						
Valtonen 1974[713]	×						
van de Weg 2004[714]	×[c]						
van den Dolder 2003[715]	×						
van den Hout 2005[91]				×			
van der Heijden 1996[716]					×[c]		
van der Heijden 1999[717]	×						
van der Windt 1997[718]							×[e]
van der Windt 1998[719]	×						
van der Windt 1999[720]					×[c]		
van der Windt 1999[721]	×						

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
van der Windt 2000[722]	×[h,t]						
van der Windt 2003[723]	×						
van Laack 1987[724]					×		
van Royen 1996[725]					×		
van Royen 1996[726]					×		
Vanni 1985[727]	×						
Vas 2008[728]	×						
Vaughn 2000[729]						×	
Venturi 1979[730]						×	
Verkhozina 1972[731]					×[d]		
Vermeulen 2004[732]	×[g]						
Vermeulen 2007[733]						×	
Verstraete 1985[734]					×[s]		
Vigano 1986[735]		×					
Volhard 1968[736]						×	
von Knorre 1990[737]	×						
Vrettos 2005[738]	×						
Wagenhau 1969[739]						×	
Walach 2003[740]	×						
Waldburger 1992[741]	×[h]						
Wallny 1997[742]					×		
Walsh 2009[743]					×[c]		
Wang 1990[744]					×		
Wang 1993[745]					×		
Wang 1995[746]					×		
Wang 1997[747]			×[d]				
Wang 2005[748]		×[o]					
Wang 2006[749]	×						
Wang 2007[750]	×						
Wang 2007[751]					×		
Wang 2008[752]		×					
Warner 1996[753]					×		
Wassef 1992[754]		×					
Watson 2000[755]	×[g]						
Weber 1995[756]					×		
Weber 2001[757]						×	
Weiser 1976[758]							×[f]
Weiser 1977[759]		×					
Wen 2009[760]	×[g,o]						
White 1995[761]				×			
White 1996[762]					×		
White 2009[763]	×						
Widiastuti-Samekto 2004[764]			×				

Study	Population	Intervention	Comparison	Outcome	Study design	Not a clinical study	Other
Wies 2003[71]	×[g]						
Wies 2003[765]	×[g]						
Wiley 1995[766]						×	
Wiley 1997[767]						×	
Winters 1995[768]	×[t]						
Winters 1997[769]	×						
Winters 1999[770]	×						
Winters 2000[771]	×[t]						
Worsdorfer 1984[772]						×	
Xiao 2006[773]					×		
Xie 1988[774]					×		
Xu 2006[775]	×[g]						
Xu 2008[776]					×[o]		
Xu 2009[777]		×[b]					
Yamaguchi 2002[778]		×					
Yamaguchi 2004[779]		×					
Yamaguchi 2008[780]						×	
Yamamoto 1988[781]	×[h,n]						
Yamamoto 1993[782]					×[n]		
Yamamoto 1993[783]			×				
Yamshon 1958[784]						×	
Yan 2005[785]	×						
Yang 2006[786]		×					
Yao 2002[787]	×[h]						
Yaya Huaman 1975[788]	×						
Yegudin-Ash 1998[789]	×						
Yigiter 2002[790]	×						
Yuan 1995[791]				×[o]			
Zachepa 1991[792]					×[d]		
Zancan 1993[793]			×[j]				
Zeilig 2005[794]	×						
Zeng 2005[795]			×[o]				
Zhang 1991[796]					×		
Zhang 1991[797]	×						
Zhang 2006[798]	×[o]						
Zhang 2008[799]	×[o]						
Zhang 2009[800]					×[o]		
Zhao 2003[801]					×		
Zhao 2006[802]			×[o]				
Zhou 2004[803]			×[o]				
Zhu 1997[804]		×[o]					
Zhu 2004[805]		×[o]					
Zivkovic 1969[806]						×	
Zuecker 1977[807]						×	

a Ongoing trial.
b Not commonly used in the UK NHS.
c Systematic review.
d Russian paper requiring English translation.
e Paper could not be obtained through the British Library.
f Foreign-language paper for which no translator could be found.
g Unclear if participants had primary frozen shoulder.
h < 90% of participants had primary frozen shoulder.
i Same study and results as Carette *et al.*[35]
j Italian paper requiring English translation.
k Same study as Dogru *et al.*[51]
l Same study as Jacobs *et al.*[85]
m French paper requiring English translation.
n Japanese paper requiring English translation.
o Chinese paper requiring English translation.
p Length of follow-up for all outcomes < 4 weeks.
q Slovakian paper requiring English translation.
r German paper requiring English translation.
s Controlled trial.
t Dutch paper requiring English translation.
u Same study as Quraishi *et al.*[38]

Appendix 6

Study details

Appendix 6.1 Steroid injection

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Bal 2008[68] RCT *Country, setting and treatment provider:* Turkey; physical therapy and rehabilitation department of a hospital	*Inclusion criteria:* Presence of shoulder pain with limitation of both active and passive movements of the glenohumeral joint of ≥ 25% in at least two directions; aged 18–70 years; symptom duration between 6 weeks and 6 months; and no treatment other than analgesics in the last 6 months *Exclusion criteria:* Uncontrolled diabetes mellitus, contraindications of injections and previous shoulder surgery *Method of diagnosis:* NR *Condition terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* Steroid injection: 56.9 (9.56); placebo injection: 56.3 (8.16) *Female:* 44% *Participants with diabetes?* Unclear/ not reported	*Duration of FS at baseline:* NR *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid injection: intra-articular, posterior approach injection of methylprednisolone acetate, 40 mg, 1 ml. One injection only. 5-cm 21-gauge needle *Home exercise*			*Placebo injection:* intra-articular, posterior approach injection of saline, 0.9% sodium chloride, 1 ml. One injection only. 5-cm 21-gauge needle *Home exercise*	Oral paracetamol (1500 mg/day) was recommended to patients when needed *Home exercise:* Five sessions daily for 12 weeks (420 sessions in total) of home exercise consisting of pendulum circumduction and passive shoulder self-stretching in forward elevation, external rotation, horizontal adduction and internal rotation. When passive range of movement reached 90% of normal range the following exercises were added: isometric in all planes, theraband exercises (low, medium and high resistance), strengthening exercises for scapular stabilising muscles, and advanced muscle strengthening exercises with dumb-bells. Participants were advised to apply a heat pack before exercise and a cold pack after exercise

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Carette 2003[35] RCT *Country, setting and treatment provider:* Canada; outpatient rheumatology clinics at seven centres; all injections performed by trained radiologists and all physiotherapy supervised by physiotherapists with at least 3 years' experience of musculoskeletal disorders	*Inclusion criteria:* Adhesive capsulitis defined as the presence of shoulder pain with limitation of both active and passive movements of the glenohumeral joint of ≥ 25% in at least two directions (abduction, flexion, external rotation, internal rotation) compared with contralateral shoulder or with normal values. Patients eligible for inclusion if they met the definition for adhesive capsulitis and were aged ≥ 18 years, had been symptomatic for < 1 year and had a total SPADI score of ≥ 30. Partway through the trial patients with diabetes mellitus became eligible to be included *Exclusion criteria:* Adhesive capsulitis secondary to another cause, including inflammatory, degenerative, metabolic or infectious arthritis, cerebrovascular accident or fracture. Known blood coagulation disorder or allergy to radiological contrast material *Method of diagnosis:* Presence of pain and range of movement *Condition terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* Steroid injection + PT: 54.9 (10.5); steroid injection: 55.4 (10.0); PT: 54.2 (8.3); placebo injection: 56.5 (9.4) *Female:* 59% *Any participants with diabetes?* Yes. Steroid injection + PT: *n* = 2 (9.5%); steroid injection: *n* = 1 (4.3%); PT: *n* = 1 (3.9%); placebo injection: *n* = 2 (8.7%)	*Duration of FS at baseline (weeks), mean (SD):* Steroid injection + PT: 22.1 (14.9); steroid injection: 21.2 (11.0); PT: 20.8 (11.2); placebo: 20.3 (7.3) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid injection + PT: Injection of triamcinolone hexacetonide, 40 mg, 2 ml into shoulder joint space using fluoroscopic guidance (intra-articular) with patient in supine position with arm by their side and in internal rotation. One injection on day of randomisation only. 2.5- to 3-inch 21-gauge needle. PT: Patients with acute symptoms: 12 × 1-hour sessions, three times per week for 4 weeks consisting of TENS, mobilisation techniques, active range of movement exercises, ice application. Patients with chronic-like symptoms: 12 × 1-hour sessions, three times per week for 4 weeks consisting of ultrasound, mobilisation techniques, active and auto-assisted range of movement exercises, isometric strengthening exercises and ice application	*Steroid injection:* Steroid injection as in combined intervention. *Home exercise*	*PT + placebo injection:* Injection of saline, 2 ml into shoulder joint space using fluoroscopic guidance. One injection on day of randomisation only. PT only as in combined intervention *Home exercise*	*Placebo injection:* Injection of saline, 2 ml into shoulder joint space using fluoroscopic guidance. One injection on day of randomisation only *Home exercise*	Patients were given a supply of paracetamol tablets. All other medications for the treatment of adhesive capsulitis were stopped *Home exercise:* Home exercises of active and auto-assisted range of movement exercises in the planes of flexion, abduction, external rotation and internal rotation, 10 minutes twice daily for 12 weeks

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Dacre 1989[87] RCT *Country, setting and treatment provider:* UK; physiotherapy was performed by a physiotherapist, the steroid was injected by a physician	*Inclusion criteria:* Criteria of Bulgen et al. (1984): painful stiff shoulder for at least 4 weeks; inability to use arm with restriction of movement and loss of full function; pain at night causing sleep disturbance and inability to lie on affected side *Exclusion criteria:* Patients with predisposing conditions were excluded *Method of diagnosis:* Clinical diagnosis (examination, radiography and erythrocyte sedimentation rate) *Terminology used:* Periarthritis of the shoulder; painful stiff shoulder	*Age (years), mean:* Steroid injection: 55.8; PT: 53.0; steroid injection + PT: 58.8 *Female:* 55% *Any participants with diabetes?* Yes. $n=3$	*Duration of FS at baseline:* NR *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid injection + PT: 20 mg triamcinolone with 1 ml 2% lidocaine was injected anteriorly. Mobilisation was the mainstay of physiotherapy (4–6 weeks' duration). The specific method was chosen by the physiotherapist	*Steroid injection:* 20 mg triamcinolone with 1 ml 2% lidocaine was injected anteriorly	*PT:* Mobilisation was the mainstay of physiotherapy (4–6 weeks' duration)		NR

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Rizk 1991[42] RCT *Country, setting and treatment provider:* USA; one physician performed all injections	*Inclusion criteria:* Total range of movement < 50% of normal range (i.e. < 320°), shoulder pain for < 6 months, nocturnal accentuation of pain, no effusion in the glenohumeral joint, no history of recent trauma, no previous injections in the involved shoulder, no history of allergy to local anaesthetics or steroids, absence of polyarthritis or neurological disease that cause shoulder pain, no evidence of alternative causes of shoulder pain revealed in radiography carried out after onset of pain and within 2 months of study entry *Method of diagnosis:* Presence of symptoms *Terminology used:* FS; adhesive capsulitis	*Age (years), mean (range):* Total: 55 (40–70); steroid (anterior) + lidocaine + PT: 55.9; steroid (lateral) + lidocaine + PT: 52.3; lidocaine (anterior) + PT: 57.7; lidocaine (lateral) + physiotherapy: 54.1 *Female:* 41.7% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (weeks), mean (range):* Total: 13.2 (8 to 18) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

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Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid (anterior approach) + PT: Once a week for 3 weeks intra-articular injection using the anterior approach (glenohumeral joint) of 1 ml repository aqueous suspension of methylprednisolone acetate (Depo-Medrol®), 40 mg/ml with 2 ml of 1% lidocaine. 1.5-inch, 21-gauge needle. Standardised weekly PT treatment for 11 weeks. Ultrasonic therapy of 1.5 W/cm^2 for 7 minutes followed by therapeutic exercise (Codman and wall climbing) *Home exercise*	*Steroid (lateral approach) + PT:* Same as for intra-articular steroid except using lateral approach (subacromial bursa) *Home exercise*	*Two arms for placebo injection: intra-articular lidocaine (anterior approach) + PT:* Once a week for 3 weeks intra-articular injection using the anterior approach of 1% lidocaine. 1.5-inch, 21-gauge needle. PT as for steroid group; *intrabursal lidocaine (lateral approach) + PT:* Once a week for 3 weeks intrabursal injection using the lateral approach of 1% lidocaine. 1.5-inch, 21-gauge needle. PT as for steroid group. *Home exercise*		Advised to continue NSAIDs prescribed by physician. All patients were receiving NSAIDs, with only minor difference in frequency distribution of various drugs between the treatment groups. Propoxyphene and other drugs were discontinued before entry into the study *Home exercise:* Instruction given in a home exercise programme (no further details provided)

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Ryans 2005[41] RCT *Country, setting and treatment provider:* UK; direct access shoulder assessment clinic run by a GP with a special interest in rheumatology at a local district hospital. Injections provided by the same experienced clinician, physiotherapy provided by a single therapist or a nominated deputy if unavailable	*Inclusion criteria:* Aged ≥ 18 years with a painful shoulder in the fifth cervical (C5) dermatone distribution of > 4 weeks' and < 6 months' duration; presence of restriction of active and passive range of movement in both external rotation and glenohumeral abduction of > 25% compared with other shoulder. *Exclusion criteria:* Previous intra-articular injection or previous physiotherapy for this episode of shoulder pain; limitation in only external rotation or glenohumeral abduction; evidence of glenohumeral osteoarthritis on radiography; clinical evidence of rotator cuff tear; history of significant trauma to the shoulder or history of inflammatory joint disease or of a cerebrovascular accident affecting the shoulder; bilateral adhesive capsulitis; patients with a contraindication to triamcinolone *Method of diagnosis:* Radiography *Terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* Steroid injection + PT: 56.3 (6.4); steroid injection: 52.3 (9.3); PT + placebo injection: 52.6 (7.7); placebo injection: 55.2 (9.4) *Female:* 59% *Any participants with diabetes?* Yes. Total: $n = 5$; steroid injection + PT: $n = 1$ (5%); steroid injection: $n = 1$ (5%); PT + placebo injection: $n = 1$ (5%); placebo injection: $n = (11\%)$	*Duration of FS at baseline (weeks), mean (SD):* Steroid injection + PT: 14.2 (4.4); steroid injection: 12.2 (5.3); PT + placebo injection: 14.4 (4.4); placebo injection: 14.9 (3.7) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* Unclear; 32% were reported to have experienced 'minor trauma'. No further details were provided

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid injection + PT: Injection of triamcinolone 20 mg, 1 ml and normal saline 2 ml using a combined non-guided approach to the shoulder: intra-articular, 1.5 ml injected by an anterior approach and 1.5 ml by a lateral approach. Physiotherapy consisted of eight sessions over 4 weeks: proprioceptive neuromuscular facilitation, Maitland mobilisations (which were progressed as the condition improved), standardised interferential modality and active exercise therapy with gym equipment *Home exercise*	*Steroid injection only:* Injection of triamcinolone 20 mg, 1 ml and normal saline 2 ml using a combined non-guided approach to the shoulder: intra-articular, 1.5 ml injected by an anterior approach and 1.5 ml by a lateral approach *Home exercise*	*PT + placebo injection:* Physiotherapy as for other group. Placebo injection of saline 3 ml using a combined non-guided approach to the shoulder: 1.5 ml injected by an anterior approach and 1.5 ml by a lateral approach *Home exercise*	*Placebo injection:* Injection of saline 3 ml using a combined non-guided approach to the shoulder: 1.5 ml injected by an anterior approach and 1.5 ml by a lateral approach *Home exercise*	Patients who were not already taking analgesics were issued with 50 × 500-mg paracetamol tablets for pain relief with suggestion to take one to two tablets 4- to 6-hourly as required for pain and taking no more than a maximum of 8 tablets daily. Patients recorded all analgesic and anti-inflammatory medication taken in a medication diary *Home exercise:* Patients were instructed by a physiotherapist in a home exercise programme using a video and home exercise instruction sheet

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

Appendix 6.2 Sodium hyaluronate

Study	Inclusion/exclusion criteria and diagnosis of frozen shoulder	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of frozen shoulder, previous treatments, secondary frozen shoulder)
Calis 2006[66] RCT *Country, setting and treatment provider:* Turkey; injection performed by a single physician	*Inclusion criteria:* History of pain for at least 1 month; limited active and passive shoulder movement; decreased passive range of movement of ≥ 20%, in at least three movements, according to the American Medical Association guide for the evaluation of permanent impairment; no previous injection in the involved shoulder; no history of allergy to local anaesthetics, steroids or sodium hyaluronate; absence of cervical radiculopathy, fracture, dislocation and rotator cuff laceration; negative subacromial impingement test *Method of diagnosis:* Physical examination and laboratory tests. Subacromial impingement test (greatly improved range of movement after injection of 1% of 5 ml lidocaine into subacromial space of affected shoulder) to exclude subacromial impingement syndrome. All tests performed by one clinician *Terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* Sodium hyaluronate injection: 59.7 (9.81); steroid injection: 56.36 (11.3); PT: 52.33 (10.1); home exercise: 59.25 (6.8) *Female:* 63% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline:* NR *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Sodium hyaluronate injection: Intra-articular, posterior approach injection of sodium hyaluronate (Orthovisc®), 30 mg, one injection once weekly for 2 weeks. 22-gauge needle used *Home exercise*	*Steroid injection:* Intra-articular, posterior approach injection of triamcinolone acetonide (Kenakort-A®), 40 mg, one injection. 22-gauge needle used *Home exercise*	*PT:* 10 daily sessions: a heat pack applied for 20 minutes; ultrasonic therapy for 5 minutes (1.5 W/cm^2 intensity); TENS for 20 minutes at patient's level of tolerance; and stretching exercises *Home exercise*	*No intervention:* Home exercise only	Paracetamol could be taken if necessary *Home exercise:* Stretching and Codman exercises

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Rovetta 1998[69] RCT *Country, setting and treatment provider:* Italy; physiotherapy delivered by one physiotherapist	*Inclusion criteria:* Clinical history of spontaneous shoulder pain; glenohumeral abduction and forward flexion < 90°, external rotation < 20°; clinical absence of signs of rotator cuff interruption; cervical examination excluding dysfunction in this area; plain radiographs in standard views; sonographic examination showing shrinking of the joint capsule with increased capsular echogenicity *Exclusion criteria:* Patients with a history of stroke, trauma, diabetes, ischaemic heart and generalised osteoarthritis disease; previous treatment with corticoid oral regimens *Method of diagnosis:* Clinical history and radiography or ultrasound *Terminology used:* Adhesive capsulitis	*Age (years), mean (?SD):* Steroid + sodium hyaluronate injection + PT: 65.8 (9.1); steroid injection + PT: 62.3 (13) *Female:* 70% *Any participants with diabetes?* No	*Duration of FS at baseline, mean (?SD):* Steroid + sodium hyaluronate injection + PT: 7.4 (? months) (4); steroid injection + PT: 9.0 (3.3) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Steroid + sodium hyaluronate injection + PT: Triamcinolone acetonide (20 mg) and sodium hyaluronate (20 mg) injection given intra-articularly (posterior approach, Cyriax and Russell) at 15-day intervals in the first month, then monthly for 6 months. The most appropriate PT was decided by physiotherapist: passive mobilisation, active exercises and facilitation exercises performed for 4–12 weeks	*Steroid injection + PT:* Triamcinolone acetonide (Bristol-Myers Squibb) (20 mg) injection given intra-articularly (posterior approach, Cyriax and Russell[808]) at 15-day intervals in the first month, then monthly for 6 months. PT as for other group			NR

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Takagishi 1996[70] RCT *Country, setting and treatment provider:* Japan; university hospital medical department	*Inclusion criteria (including definition of FS):* Patients with FS who have <120° of shoulder joint flexion and those who suffer from pain on exercise of >4 on the VAS and suffer from pain during night-time and daytime *Exclusion criteria:* Previous shoulder injury *Method of diagnosis:* Clinical examination *Terminology used:* Gojukata (Japanese; English translation 'Fifties shoulder')	*Age (years), mean:* Sodium hyaluronate: 56; steroid: 48 *Female:* 75% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (months), mean:* Sodium hyaluronate: 4.4; steroid: 3.5 *Stage of FS at baseline:* NR

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Sodium hyaluronate: one intra-articular injection of 2 mg sodium hyaluronate once a week for 5 weeks	*Steroid injection:* one intra-articular injection of 2 mg dexamethasone once a week for 5 weeks			Topical NSAIDs

FS, frozen shoulder; NR, not reported, PT, physiotherapy.

Appendix 6.3 Acupuncture

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Cheing 2008[81] RCT *Country, setting and treatment provider:* Hong Kong; treatment delivered by physiotherapist accredited to deliver acupuncture. The same individual delivered all of the treatments	*Inclusion criteria:* Localised pain over one shoulder, night pain and restricted active and passive shoulder motion *Exclusion criteria:* History of trauma, fractures, previous shoulder surgery, cervical or thoracic pain syndrome, complex regional pain syndrome, malignancies or anticoagulant therapy or acupuncture treatment to the painful shoulder in the previous 6 months *Method of diagnosis:* Diagnosed by orthopaedic surgeon *Terminology used:* FS; adhesive capsulitis	*Age (years), range:* 33 to 90 *Female:* NR *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (months), mean (SD):* Electroacupuncture: 6.71 (6.50); interferential electrotherapy: 6.70 (6.05); control: 8.26 (7.94) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Electroacupuncture: 10 sessions, two to three times per week, over a 4-week period. Three points needled (one trigger point, LI15 and ST38) with a needle of 0.30 × 40 mm diameter, at a depth of 15–25 mm. 'De qi' sensation was felt by the patient and 2–100 Hz electrical stimulation was used at a pulse duration of 100–400 μs (just below pain threshold) for 20 minutes *Home exercise*	*Interferential electrotherapy:* 10 × 20-minute sessions over 4 weeks at 80–120 Hz. Four suction-type electrodes were placed around the shoulder region in a coplanar arrangement *Home exercise*		*No intervention:* Waiting list controls	NR *Home exercise:* Participants followed a chart and performed a standard set of mobilisation exercises five times per day over 6 months that included four directions (forward flexion, external rotation, horizontal adduction, internal rotation)

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Fang 2006[82] RCT *Country, setting and treatment provider:* China; Hospital outpatient department	*Inclusion criteria:* Used recognised criteria *Exclusion criteria:* Aged > 65 years, too sensitive to electrotherapy, fracture of shoulder, receiving long-term concomitant medication *Method of diagnosis:* Clinical examination *Terminology used:* Periarthritis of the shoulder	*Age (years), mean (SD):* TENS: 51.5 (3.1); electroacupuncture: 52.9 (3.8) *Female:* 55% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (weeks/months??), mean (SD):* TENS: 6.1 (3.5); electroacupuncture: 6.8 (3.2) *Stage of FS at baseline:* Stage 1 (pre-adhesive): Patient feels pain around the shoulder, with increased pain at night (which even affects quality of sleep). The ranges of motion (or functional activities of the shoulder) are normal or slightly affected. Stage 2 (adhesive): Patient feels some reduction in pain but feels uncomfortable because of the pain. The functional activities of the shoulder are seriously affected; the ranges of motion are considerably reduced, which even affects activities of normal life *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Electroacupuncture: 10 × 40-minute sessions every other day. Four acupuncture points [Waiguan (SJ5) and Hegu (LI4) and, alternating each session, Jianliao (SJ14) and Jian qian (Ex-UE), or Jianyu (LI15) and Naoshu (SI10)]. 0.30 mm × 40 mm needles inserted to depth of 20–25 mm. Electricity was administered after De qi was felt (not reported whether De qi was felt by acupuncturist or by patient)	*TENS:* 10 × 40-minute sessions every other day. Electrodes placed at four acupuncture points [Waiguan (SJ5) and Hegu (LI4) and, alternating each session, Jianliao (SJ14) and Jian qian (Ex-UE), or Jianyu (LI15) and Naoshu (SI10)]. High frequency (100 Hz) for 10 minutes and low frequency (2 Hz) for 30 minutes. Intensity of current 10 ± 2 mA			NR

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Ma 2006[83] RCT *Country, setting and treatment provider:* Taiwan; medical centre	*Inclusion criteria:* Shoulder pain for at least 3 months, could not lift arms more than 135° *Exclusion criteria:* Non-spontaneous FS caused by nervous system diseases, acute inflammation and broken bones; acupuncture syncope and skin infection surrounding acupuncture points *Method of diagnosis:* Clinical history *Terminology used:* FS	*Age (years), mean:* PT: 54.1; acupuncture: 56.4; acupuncture + PT: 52.8 *Female:* 52% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (weeks), mean:* 25.8 *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Acupuncture: 15-minute session twice a week for 4 weeks. Each session consisted of therapeutic principles in promoting flow of qi and blood, driving out the wind and cold, removing dampness and activating meridians; therapeutic methods on three yang meridians of the hand; and prescriptions with jianliao, jianlu (LI15), fengchi (GB20), hegu (L14) and yanglingquan (GB34)	Acupuncture + PT: Acupuncture as for other group. Five sessions of physiotherapy per week for 4 weeks. Each session consisted of heat pack for 15 minutes, joint mobilisation for 5–10 minutes and active shoulder exercises for 5–10 minutes	PT: Five sessions of physiotherapy per week for 4 weeks. Each session consisted of heat pack for 15 minutes, joint mobilisation for 5–10 minutes and active shoulder exercises for 5–10 minutes		NR

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

Appendix 6.4 Physical therapy

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Diercks 2004[73] Controlled trial *Country, setting and treatment provider:* Netherlands; NR	*Inclusion criteria:* Idiopathic FS diagnosed between January 1997 and January 2001; the Lundberg criteria were used (> 50% motion restriction of the glenohumeral joint in all directions for at least 3 months) *Exclusion criteria:* Patients with significant injury to the ipsilateral shoulder or arm, with surgical procedures on the shoulder, arm, cervical spine, thorax or breast within the previous 2 years or with intra-articular deformities, degenerative arthritis, inflammatory arthritis or diabetes mellitus were excluded *Method of diagnosis:* Glenohumeral joint movement was measured using a Cybex inclinometer *Terminology used:* FS	*Age (years), mean (SD):* Supervised neglect: 50 (6); PT: 51 (7) *Female:* 61% *Any participants with diabetes?* No	*Duration of FS at baseline (months), ?mean (range):* Supervised neglect: 5 (3 to 12); PT: 5 (3 to 10) *Stage of FS at baseline: NR* *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
PT: Patients were prescribed a standardised treatment protocol, carried out by a physical therapist, of active exercises up to and beyond the pain threshold, passive stretching and manipulation of the glenohumeral joint and home exercises aimed at stretching and maximal reaching. Duration was not reported *Home exercise*			*Supervised neglect:* Patients were provided with an explanation of the natural course of the disease and were instructed not to exercise in excess of their pain threshold and to carry out pendulum exercises and active exercises within this painless range and resume all activities that were tolerated. Duration was not reported *Home exercise*	NSAIDs or analgesics were prescribed to both groups where necessary

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Dogru 2008[51] RCT *Country, setting and treatment provider:* Turkey; outpatient clinic	*Inclusion criteria:* Shoulder pain of at least 3 months' duration and no major trauma; at least 25% loss of shoulder motion in all planes; pain on motion of at least 40 mm on VAS; normal findings on radiograph of the glenohumeral joint; absence of arthritis, malignancy and conditions such as cardiac disease, infection and coagulation disorders *Exclusion criteria:* Secondary adhesive capsulitis due to rotator cuff tears, fractures, dislocations and reflex sympathetic dystrophy *Method of diagnosis:* Routine systemic and neurological examination and measurement of active and passive range of movement. Passive range of movement was measured in all planes with a long-arm goniometer while patient supine. Complete blood count, erythrocyte sedimentation rate and routine biochemical analysis for exclusion of secondary factors. Shoulder radiographs were taken *Terminology used:* Adhesive capsulitis	*Age (years), mean (?SD):* Total: 55.4 (7.6); ultrasound + PT: 53.9 (7.8); sham ultrasound + PT: 56.8 (7.3) *Female:* 57% *Any participants with diabetes?* Yes. Total: n = 18 (37%); ultrasound + PT: n = 8 (32%); sham ultrasound + PT: n = 10 (42%)	*Duration of FS at baseline (months), mean (?SD, range):* Total: 5.7 (3.3, 3 to 12); ultrasound + PT: 6.3 (3.5); sham ultrasound + PT: 5.2 (2.9) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Ultrasound + PT: 10 daily sessions of 50 minutes over 2 weeks (no treatment at weekends). Each session consisted of 20 minutes of superficial heat (heat packs at 60°C), 10 minutes of ultrasound (3 MHz frequency and 1.5 W/cm^2 intensity) and a 20-minute exercise programme (Codman's exercises and wall climbing followed by glenohumeral joint stretching exercises to the patient's tolerance) *Home exercise*	*Sham ultrasound + PT:* Same as ultrasound intervention except the ultrasound machine was not switched to 'on' *Home exercise*			Paracetamol, maximum of 1000 mg/day *Home exercise:* A daily exercise programme consisting of Codman's exercises, active ROM and stretching exercises

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Dundar 2009[74] RCT *Country, setting and treatment provider:* Turkey; ?hospital	*Inclusion criteria:* FS patients with gradually increasing shoulder pain and stiffness (painful phase and stiff phase) *Exclusion criteria:* Patients with rotator cuff pathology or those with secondary FS or stiff shoulder associated with a fracture, arthritis, abnormal shoulder radiographs or any significant trauma were excluded *Method of diagnosis:* Diagnosis was made on the basis of history, physical examination, radiography findings and, occasionally, magnetic resonance imaging, by specialists in physical medicine and rehabilitation. All patients had radiography of the shoulder joint *Terminology used:* FS	*Age (years), mean (SD):* Continuous passive motion: 56.3 (7.8); conventional PT: 57.1 (8.3) *Female:* 68% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (months), mean (SD):* Continuous passive motion: 6.3 (4.2); conventional PT: 5.9 (4.0) *Stage of FS at baseline:* Patients with phase 1 and/or phase 2 FS were included *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Continuous passive motion: Treatments involved a gradual increase in motion for 1 hour per day for 20 days over 4 weeks (5 days per week) using an external motorised device *Home exercise*	*Conventional PT:* Daily physiotherapy by a physiotherapist involving active stretching and pendulum exercises for 1 hour per day for 20 days over 4 weeks (5 days per week) *Home exercise*			No NSAIDs or other analgesics allowed. A 1-week washout period was required before therapy *Home exercise:* A standardised home exercise programme of passive range of movement and pendulum exercise every day until week 12. This was demonstrated by a physiotherapist on one occasion and written advice was given

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Leung 2008[75] RCT *Country, setting and treatment provider:* Hong Kong; NR	*Inclusion criteria:* Patients with idiopathic FS who experienced shoulder pain and limited shoulder movement for at least 8 weeks *Exclusion criteria:* Patients with history of trauma to the shoulder, acute signs of shoulder inflammation and intrinsic shoulder pathology; patients with impaired sensation of hot and cold; pregnant patients; patients taking analgesic or anti-inflammatory drugs, with metal implants or with a cardiac pacemaker *Method of diagnosis:* Diagnosis made by orthopaedic surgeon *Terminology used:* FS	*Age (years), mean (SD):* SWD + stretching: 59.8 (12.9); heat pack +stretching: 62.5 (12.1); stretching only: 57.3 (13.1) *Female:* 70% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline:* NR *Stage of FS at baseline:* Stiff phase *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
SWD + stretching: Treatment was 3×20-minute sessions per week for 4 weeks. SWD machine with an operating frequency of 27.12 MHz was used. Patients sat on a wooden chair with back and affected arm supported and a pair of disc electrodes were placed on the affected glenohumeral joint. The intensity of the current was adjusted according to the patient's subjective feeling of warmth and to maintain the feeling of comfortable warmth throughout. Immediately after heat treatment four stretching exercises were performed in a fixed sequence (stretching in external rotation and in flexion followed by stretching hand behind back and cross-body adduction). Each stretch was sustained for 30 seconds with a 10-second rest between stretches *Home exercise*	*Heat pack + stretching:* Superficial heat was delivered using an electrical heat pack (35.5×68.5 cm). The temperature was set to 63°C but patients were informed that heating was to produce a feeling of comfortable warmth and if the heat was felt to be excessive this was adjusted. Stretching exercises as for SWD *Home exercise*		*No intervention:* Home exercise only	*Home exercise:* Patients were asked to perform stretches at home every day

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Maricar 1999[76] RCT *Country, setting and treatment provider:* Singapore; NR	*Inclusion criteria:* Major complaint of limitation in shoulder range of movement with secondary complaint of pain; able to place arms behind head and back reaching vertebral column; 90-degree abduction *Exclusion criteria:* History of previous shoulder trauma or previous episode of FS; existing or previous diagnosis of several other conditions (detailed in paper) including uncontrolled diabetes *Method of diagnosis:* Diagnosis (late stage 2 to stage 3) determined by the research physiotherapist. Radiographs were also reviewed *Terminology used:* FS; shoulder capsulitis	*Age (years), mean (SD):* Manual therapy + exercise: 57.9 (9.5); exercise only: 54.9 (5.4) *Female:* 41% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline:* Average duration for both groups: 3 months (two patients in each group had onset between 6 months and <2 years) *Stage of FS at baseline:* Late stage 2 or stage 3 *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Manual therapy + exercise: Manual therapy (mobilisation of the shoulder quadrant, shoulder capsular stretch, shoulder flexion, shoulder abduction, shoulder external and internal rotation using Maitland grade III+ and IV) for eight weekly sessions. A 15-minute exercise circuit of nine exercises was also performed (including a strengthening regime for the rotator cuff muscles from week 5 onwards) *Home exercise*	*Exercise only:* A 15-minute exercise circuit of nine exercises (including a strengthening regime for the rotator cuff muscles from week 5 onwards) *Home exercise*			*Home exercise:* Home exercises were taught by a research physiotherapist and exercise sheets issued

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Pajareya 2004[77] RCT *Country, setting and treatment provider:* Thailand; hospital based; therapy delivered by three physiotherapists whose performance had been standardised	*Inclusion criteria:* Shoulder pain and limitation of a passive range of shoulder motion in all directions that interfered with activities of daily living; attendance at the orthopaedic and rehabilitation clinic at Siriraj Hospital *Exclusion criteria:* Secondary adhesive capsulitis; intrinsic or extrinsic causes of shoulder problems; generalised arthritis; bilateral involvement; contraindications for NSAIDs; bleeding tendencies *Method of diagnosis:* NR *Terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* PT: 56.3 (10.6); standard care: 57.7 (10) *Female:* 68% *Any participants with diabetes?* Yes. Total: $n=20$; PT: $n=10$ (16.7%); standard care: $n=10$ (16.7%)	*Duration of FS at baseline:* PT: <6 weeks: $n=13$; 6 to <12 weeks: $n=20$; at least 12 weeks: $n=27$; standard care: <6 weeks: $n=6$; 6 to <12 weeks: $n=20$; at least 12 weeks: $n=33$ *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* Unclear/NR; 47% reported history of minor trauma before onset

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
PT: Three times per week for 3 weeks consisting of SWD (20 minutes), mobilisation and passive glenohumeral joint stretching exercises to the patient's tolerance. On non-PT days patients were advised to perform pulley exercises (actively assisted exercises for 5 minutes) and active non-assisted exercises using a towel and wall (5 minutes after applying a heat pack for 20 minutes). The exercise guideline was based on Cyriax. Exercise was contraindicated if the patient felt pain with the passive movements before the end of the range			*No intervention:* Information only	Ibuprofen (400 mg, three times daily, for 3 weeks) Patients were asked not to have any adjuvant therapy except oral paracetamol (up to 6 g/day) An information sheet advising on protection of the shoulder from vigorous activities was also given. Patients were encouraged to use their arms in a normal fashion for other activities of daily living

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Stergioulas 2008[16] RCT *Country, setting and treatment provider:* Greece; Peania Physical Therapy Centre; physiotherapists performed treatment	*Inclusion criteria:* Painful and limited passive glenohumeral mobility; more restricted lateral rotation (<8%) relative to abduction and medial rotation; no clear signs that shoulder pain was caused by another condition *Exclusion criteria:* Insulin-dependent diabetes; bilateral symptoms; systemic inflammatory joint disease; corticosteroid or physiotherapy treatment in preceding 6 months; surgery, dislocation or fracture/s of shoulder; calcification of the shoulder joint; complete rotator cuff tear *Method of diagnosis:* History of limited movement of glenohumeral joint, with pain at the available range of motion. Clinical history *Terminology used:* FS	*Age (years), mean (SD):* Laser: 55.5 (5.8); sham laser: 56.8 (6.8) *Female:* 37% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (weeks/months??), mean (?SD):* Laser: 26.5 (12.8); placebo: 27.1 (13.6) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* Unclear/NR

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Laser therapy: 3B Laser M1 1000 (a Ga-Al-As laser) applied around shoulder joint (810 nm, continuous mode, 60 mW, spot size 0.5 cm^2, duty cycle 50%, 3.6 J/cm^2) for 30 seconds over 8 weeks (12 sessions; two per week in the first 4 weeks, then one per week). Dose per point was 1.8 J; total dose/session 14.4 J. *Home exercise*			*Placebo laser:* Placebo laser that appeared identical to active laser was used for the same regimen as active laser (12 sessions over 8 weeks; two per week in the first 4 weeks, then one per week) *Home exercise*	Not reported *Home exercise:* Patients were instructed to perform pendulum and pain-free active exercises at home

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Vermeulen 2006[40] RCT *Country, setting and treatment provider:* Netherlands; outpatient clinic of Department of Physical Therapy at Leiden University Medical Centre; physical therapists performed treatment	*Inclusion criteria:* ≥50% loss of passive movement of shoulder joint relative to non-affected side, in one or more of three movement directions (abduction in frontal plane, forward flexion or external rotation); duration of complaints of ≥3 months; ability to complete questionnaires in Dutch *Exclusion criteria:* Previous MUA of the affected shoulder; other conditions involving the shoulder (e.g. rheumatoid arthritis, osteoarthritis, damage of the glenohumeral cartilage, Hill–Sachs lesion, osteoporosis, malignancies in the shoulder region); neurological deficits affecting shoulder function in normal daily activities; pain or disorders of the cervical spine, elbow, wrist or hand; and injection with corticosteroid in the affected shoulder in the preceding 4 weeks *Method of diagnosis:* NR *Terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* HGMT: 51.6 (7.6); LGMT: 51.7 (8.6) *Female:* 66% *Any participants with diabetes?* Yes. Total: *n*=16: HGMT: *n*=8 (16%); LGMT: *n*=8 (16%)	*Duration of FS at baseline (months), mean (range):* HGMT: 8 (5 to 14.5); LGMT: 8 (6 to 14) *Stage of FS at baseline:* NR *Previous treatments for FS:* Previous PT: HGMT: *n*=39 (79%), LGMT: *n*=42 (82%); previous steroid injections: HGMT: *n*=32 (65%), LGMT: *n*=29 (57%); previous surgery: HGMT: *n*=3 (6%), LGMT: *n*=3 (6%) *Participants with secondary FS:* No

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
HGMT: One 30-minute session twice weekly for a maximum of 12 weeks consisting of 5-minute assessment of range of movement by performing all three physiological movements of the glenohumeral joint passively. At each position of the shoulder, the end-feel movement was assessed in order to apply the mobilisation technique into the stiffness zone. Mobilisation techniques were applied with intensities according to Maitland grades III and IV. The duration of prolonged stress on the shoulder capsule in the end-range position varied according to the participant's tolerance. Participants were instructed to inform the therapist about the degree and nature of the pain during and after treatment. If the pain influenced the execution of mobilisation techniques by increasing the reflex muscle activity, then the therapist altered the direction or degree of mobilisation. If pain worsened or continued for more than 4 hours the intensity of the mobilisation technique was decreased in the next session	*LGMT:* One 30-minute session twice weekly for a maximum of 12 weeks consisting of 5-minute assessment of range of movement by performing all three physiological movements of the glenohumeral joint passively. At each position of the shoulder, the end-feel movement was assessed in order to apply the mobilisation technique within the pain-free zone. Participants were informed that all techniques should be performed without causing pain in the shoulder. Mobilisation techniques were performed according to Maitland grades I and II. Reflex muscle activity was monitored for indications of joint pain. If joint mobility increased, then mobilisation techniques were adjusted, and the amplitudes of movements were increased without reaching the limits of range of movement. For the last 3 minutes of each treatment passive proprioceptive neuromuscular facilitation patterns within the pain-free zone in the supine position were applied. Codman pendular exercises were performed for 2 minutes in a prone position			Pain medication, prescribed and non-prescribed, was allowed. No other concomitant treatments for FS, including intra-articular corticosteroid injections into any joint, were allowed in the first 3 months *Home exercise:* Neither treatment group received a home exercise programme but both were advised to use the affected shoulder in daily activities whenever possible

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Yang 2007[78] RCT *Country, setting and treatment provider:* Taiwan; therapy delivered by a single physical therapist with 8 years' experience in manual therapy *Note:* Because of limitations in the study design and data reported, only data comparing ERM + MRM with MWM + MRM at 6 weeks were extracted	*Inclusion criteria:* Painful stiff shoulder for at least 3 months; range of movement losses of at least 25% compared with the non-involved shoulder in at least two of glenohumeral flexion, abduction or medial or lateral rotation *Exclusion criteria:* Diabetes mellitus, history of surgery on relevant shoulder, rheumatoid arthritis, painful stiff shoulder after severe trauma, fracture of shoulder complex, rotator cuff rupture, tendon calcification *Method of diagnosis:* NR *Terminology used:* FS	*Age (years), mean (SD):* ERM + MRM: 53.3 (6.5); MWM + MRM: 58 (10.1) *Female:* 86% *Any participants with diabetes?* No	*Duration of FS at baseline (weeks), mean (SD):* ERM + MRM: 18 (8); MWM + MRM: 22 (10) *Stage of FS at baseline:* Stiff phase *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
ERM + MRM: Mobilisation techniques were given in the following order: MRM (Maitland[809] and Kaltenborn[810]) 10–15 repetitions, ERM (Vermeulen *et al.*[811] and Maitland[809]) 10–15 repetitions, MRM (Maitland[809] and Kaltenborn[810]), MWM (Mulligan[812]) 3 sets of 10 repetitions. There were 3 weeks in each phase. Mobilisation techniques were performed twice per week for 30 minutes. A simple exercise programme comprising pendular exercises and scapular setting (isometric scapular retraction) was also given	*MWM + MRM:* Mobilisation techniques were given in the following order: MRM (Maitland[809] and Kaltenborn[810]), MWM (Mulligan[812]), MRM (Maitland[809] and Kaltenborn[810]), ERM (Vermeulen *et al.*[811] and Maitland[809]). Technique as for other group			No other interventions allowed (including other physical therapies) *Home exercise:* Home exercise was discouraged

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Yan 2005[72] RCT *Country, setting and treatment provider:* China; primary care	*Inclusion criteria:* 'Standard shoulder periarthritis diagnostic criteria in "Clinical pain therapy"' *Exclusion criteria:* Patients with functional disability due to neural-, muscle- or bone-related diseases *Method of diagnosis:* Clinical examination *Terminology used:* FS	*Age (years), mean (SD):* Dumb-bell gymnastics: 56.6 (12.4); bare-handed exercise: 54.2 (11.6) *Female:* 20% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (years), mean:* Dumb-bell gymnastics: 6.8; barehanded exercises: 5.8 *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None stated

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Dumb-bell gymnastics: Exercises performed 5–10 minutes, two to three times a day for 3 months using dumb-bells weighing 2–5 kg	*Barehanded exercises:* Bare-handed exercises performed for 3 months			NR

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Wies 2003[71] RCT *Country, setting and treatment provider:* UK; NR	*Inclusion criteria:* NR (all patients had been diagnosed with primary FS; confirmed through correspondence with author) *Exclusion criteria:* NR *Method of diagnosis:* NR *Terminology used:* FS	*Age:* NR *Female:* NR *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline:* NR *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* No

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
PT: Physiotherapy consisting of manual therapy and therapeutic exercise for 9 weeks. No further details reported	*Osteopathy technique:* The Niel-Asher technique, consisting of a progression of deep-tissue manipulation, for 9 weeks	*Control:* Breathing exercises, effleurage massage and pain-free range of movement exercises for 9 weeks		NR

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

Appendix 6.5 Manipulation under anaesthesia

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Amir-us-Saqlain 2007[84] RCT *Country, setting and treatment provider:* Pakistan; orthopaedic outpatients department	*Inclusion criteria:* History of pain and stiffness of the shoulder joint for which no cause could be identified, restriction of glenohumeral motion of < 50% of abduction and < 50% of external rotation compared with the motion of the contralateral shoulder joint and normal radiography finding in the shoulder joint. All symptoms had to be of 3 weeks' duration *Exclusion criteria:* Intrinsic problems with the shoulder, such as recent surgical repair of soft tissue of the shoulder, history of fracture around shoulder joint, instability and recurrence following previous manipulation, significant osteopenia, tear of the rotator cuff, arthritis involving the glenohumeral or acromioclavicular joint, sympathetic dystrophy and abnormality of plain radiography of the shoulder joint. Extrinsic problems such as a neuromuscular disorder (Parkinsonism) or referred pain from an associated condition, such as extrusion of cervical disc with radiculopathy *Method of diagnosis:* Standardised physical examination in upright position; active and passive range of movement of both shoulders was measured using a standard goniometer. Shoulder radiographs were taken *Terminology used:* FS; adhesive capsulitis	*Age (years), mean (range):* Total: 54 (38 to 65) *Female:* 61% *Any participants with diabetes?* Unclear/ NR	*Duration of FS at baseline (weeks), mean (range):* Total: 10 (3 weeks to 10 months) *Stage of FS at baseline:* 67% pain and stiffness, 12% pain, 21% stiffness *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT: Local injection of 80 mg Kenacort combined with 2% Xylocaine in shoulder joint 1 cm distal and 1 cm lateral to coracoid process. Manipulated extremity was kept in 160° of abduction, with 90° of external rotation, using a cotton bandage secured to the wrist and tied to the back of the bed for 24 hours. Patients were allowed to untie their extremity for toileting only. All patients were discharged after 24 hours with daily physiotherapy sessions of 30 minutes for 3 weeks	*MUA + steroid injection + PT:* Local injection of 80 mg Kenacort combined with 2% Xylocaine in shoulder joint 1 cm distal and 1 cm lateral to coracoid process. All patients were discharged after 24 hours with daily physiotherapy sessions of 30 minutes for 3 weeks			NR

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Jacobs 2009[85] RCT *Country, setting and treatment provider:* UK; MUA performed by orthopaedic surgeon. MUA patients shown exercises by physiotherapist. Distension with steroids performed in hospital orthopaedic outpatient department	*Inclusion criteria (including definition of FS):* Consecutive patients who presented to the upper limb service at the Royal Oldham Hospital with primary FS *Exclusion criteria:* Type 1 or 2 diabetes and other medical conditions known to be associated with FS; steroid injection in the affected shoulder before referral *Method of diagnosis:* Medical history; clinical examination including radiography *Terminology used:* FS; adhesive capsulitis	*Age (years), median:* MUA: 56.5; steroid injection + distension: 57 *Female:* 66% *Any participants with diabetes?* No	*Duration of FS at baseline (weeks), median:* MUA: 19; steroid injection + distension: 16 *Stage of FS at baseline:* Most patients were in 'freezing phase' of FS (based on duration of symptoms) *Previous treatments for FS:* NR *Participants with secondary FS:* No

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
MUA: Anaesthetised patients were positioned on the opposite side to that being manipulated. The assistant placed the heel of the hand on the lateral border of the ipsilateral scapula to stabilise it. Using a short lever arm, the patient's arm was manipulated into full adduction and forward flexion, full external rotation, full internal rotation and, finally, full abduction. All patients were treated as day cases *Home exercise*	*Steroid injection + distension:* Three steroid and distension treatments at 6-week intervals. The injection consisted of 1 ml of triamcinolone (40 mg), 5 ml of 2% lidocaine, 10 ml of 0.25% bupivacaine and 5 ml of air and was given by the posterior route. The needle was inserted 1–2 cm below the corner of the acromion into the 'soft spot' and directed towards the index finger, entering the glenohumeral joint. The air provides a palpable and occasionally audible 'squelch' confirming that the injection is in the glenohumeral joint and that the joint capsule has not been ruptured by the injection *Home exercise*			NR *Home exercise:* For MUA as shown by the physiotherapist; the steroid injection group was given a sheet detailing the same exercises

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Kivimaki 2007[39] RCT *Country, setting and treatment provider:* Finland; three regional hospitals in southern Finland; a physician performed MUA and physiotherapists gave physiotherapy advice	*Inclusion criteria:* Adult patients with gradually increasing shoulder pain and stiffness; shoulder mobility of no more than 140° in elevation and 30° in external rotation *Exclusion criteria:* Arthritis, osteoarthritis or traumatic bone or tendon changes in the affected shoulder; in patients with weak external rotation or abduction ultrasound examination was performed and patients with verified rotator cuff rupture were excluded *Method of diagnosis:* Specialists in physical medicine and rehabilitation diagnosed FS by radiography and measuring range of movement *Terminology used:* Frozen shoulder	*Age (years), mean (SD):* MUA: 53 (8.4); control: 53 (8.6) *Female:* 68% *Any participants with diabetes?* Yes. 18 patients (reported as equal in both groups)	*Duration of FS at baseline:* Mean duration of shoulder pain was 7 months in both groups (range 3 to 22 months) *Stage of FS at baseline:* Stiff and painful *Previous treatments for FS:* In the 3 months before randomisation no differences were reported between groups regarding reported physiotherapy, massage or chiropractic manipulations, and patients had used analgesics for 36 days equally in both groups *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
MUA + PT: Manipulations were performed < 2 weeks after randomisation under short general anaesthesia. Patients were supine and, after confirming the capsular contracture, the physician lifted the affected extremity and pushed the upper arm into flexion and abduction while supporting the scapula against the thoracic cage. After the shoulder was stretched into flexion the elbow was raised to a right angle and the upper arm was gently rotated into internal and external rotation. Any cracking sound in the shoulder joint during manipulation was recorded. Normal or near-normal mobility was achieved. The patients received physiotherapy advice in two sessions and written instructions for a daily training programme (home exercise)			*Home exercise:* The patients received physiotherapy advice in two sessions and written instructions for a daily training programme (home exercise)	The most frequently used treatment was a prescription for analgesics. *Home exercise:* Daily training programme that included pendulum exercises for the arm and stretching exercises for the shoulder joint

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Quraishi 2007[38] RCT *Country, setting and treatment provider:* UK; MUA performed by consultant orthopaedic surgeon; arthrographic distension performed by radiologist	*Inclusion criteria:* Aged > 18 years, stage II adhesive capsulitis, global loss of active and passive shoulder movement, restriction of rotation < 50% of normal and normal anteroposterior and axillary lateral radiography of the glenohumeral joint *Exclusion criteria:* Post-traumatic or other extrinsic cause, suspected osteoporosis, unfit for general anaesthesia *Method of diagnosis:* Clinical assessment by consultant surgeon *Terminology used:* Adhesive capsulitis	*Age (years), mean (range):* MUA: 54.5 (36 to 69); arthrographic distension: 55.2 (44 to 70) *Female*: 58% *Any participants with diabetes?* Yes. Total: *n* = 6; MUA: *n* = 3 (18%, all type 1); arthrographic distension: *n* = 3 (16%, all type 1)	*Duration of FS at baseline (weeks), mean (range):* MUA: 39.8 (16 to 102); arthrographic distension: 37.4 (12 to 76) *Stage of FS at baseline:* Stage II primary adhesive capsulitis *Previous treatments for FS:* Physiotherapy: *n* = 16; steroid injection: *n* = 22; physiotherapy + steroid injection: *n* = 11 *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
MUA + steroid injection: Restoration of shoulder movement following a specific protocol to ensure safe breakage of adhesions by using a short lever arm. 2 ml of 2% lidocaine and 0.75 ml (30 mg) of triamcinolone acetonide was injected anteriorly into the glenohumeral joint without guidance *Home exercise*	*Arthrographic distension:* Needle inserted into glenohumeral joint using anterior approach. Position of needle was checked by image intensifiers before and after injection of radio-opaque contrast material. Normal saline (10–55 ml) was then injected to progressively distend the capsule until it ruptured, which was usually through the subscapularis bursa, but occasionally down the biceps sheath *Home exercise*			NR *Home exercise:* Self-exercise programme of pendular exercises and wall-climbing movements

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

Appendix 6.6 Distension

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Buchbinder 2004[43] RCT *Country, setting and treatment provider:* Australia; single radiologist; community-based rheumatology practice	*Inclusion criteria:* Aged > 18 years, pain and stiffness in predominantly one shoulder for ≥ 3 months, restriction of passive range of movement of > 30° in two or more planes of movement, measured to onset of pain *Exclusion criteria:* Severe pain at rest (> 7 out of 10 on VAS), previous arthrographic distension, systemic inflammatory joint disease (including rheumatoid arthritis, polymyalgia rheumatica); radiological evidence of osteoarthritis of the shoulder or fracture, calcification about the shoulder joint, reason to suspect a complete rotator cuff tear *Method of diagnosis:* Passive range of movement was measured to onset of pain using a gravity inclinometer; radiography *Terminology used:* Painful stiff shoulder	*Age (years), mean (SD):* Arthrographic distension: 57.2 (8.6); sham distension: 57.5 (8.1) *Female*: 80% *Any participants with diabetes?* Yes. Arthrographic distension: *n* = 8 (32%); sham distension: *n* = 5 (24%)	*Duration of FS at baseline (days), median (range):* Arthrographic distension: 118 (102 to 194); sham distension: 114 (96 to 402) *Stage of FS at baseline:* Not reported *Previous treatments for FS:* Previous corticosteroid injection: arthrographic distension: *n* = 7 (28%); sham distension: *n* = 6 (28.6%) *Participants with secondary FS:* Yes. Total: *n* = 1 (2.2%); arthrographic distension: *n* = 0; sham distension: *n* = 1 (postoperative capsulitis)

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Arthrographic distension + steroid: Participants were in a supine position with the affected arm externally rotated and a sandbag on the hand. The image intensifier was centred on the glenohumeral joint, cone open to include scapula and upper third of the humerus, and the image intensifier to table top distance set at 50 cm. The skin was marked for arthrogram needle site and infiltrated with local anaesthetic. The arthrogram needle was positioned, connected to the connector tap and tube and 0.5–1 ml of contrast injected and a radiographic image taken; 40 mg of methylprednisolone acetate (Depo-Medrol®, 1 ml) and up to 82 ml of normal saline was then injected (total volume 30–90 ml). The end point of the procedure was filling of the subscapular bursa, capsular rupture, injection of the total volume of liquid or the participant requesting termination of the procedure *Home exercise*			*Placebo:* Arthrogram only. Same as for intervention except that there was no injection of steroid and saline *Home exercise*	Paracetamol; codeine preparations allowed. Participants were asked to stop taking any NSAIDs No manual treatment (e.g. physiotherapy, massage, chiropractic) or other medical interventions (e.g. intra-articular steroid injection) were allowed *Home exercise:* Participants received a simple exercise programme comprising pendular exercises and scapular setting (isometric scapular retraction)

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Gam 1998[86] RCT *Country, setting and treatment provider:* Denmark; hospital	*Inclusion criteria:* FS of > 6 weeks' duration; aged between 18 and 70 years; nocturnal accentuation of pain; passive range of shoulder external rotation < 50% of opposite shoulder; no effusion in glenohumeral joint; normal radiography of affected shoulder; normal erythrocyte sedimentation rate, haemoglobin, leucocytes and alkaline phosphatase and negative immunoglobulin M rheumatoid factor *Exclusion criteria:* Trauma to shoulder in previous 6 months that caused pain or restricted movement of shoulder within 1 week (trivial minor injuries accepted); diabetes; treatment for FS (except analgesics) during study period *Method of diagnosis:* Diagnosis by authors. Diagnosis was defined after clinical examination, blood samples and radiography or diagnostic ultrasound *Terminology used:* FS; adhesive capsulitis; scapulohumeral periarthritis	*Age (years), median (25–75 percentiles):* Steroid injection: 47 (43–54); steroid injection + distension: 53.5 (50–63) *Female:* 59% *Any participants with diabetes?* No	*Duration of FS at baseline (months), median (25–75 percentiles):* Steroid injection: 4.5 (3.3–5.8); steroid injection + distension: 5 (4.3 –6.0) *Stage of FS at baseline:* NR *Previous treatments for FS:* NR *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Distension + steroid: Intra-articular injection, confirmed by ultrasound, of 20 mg of triamcinolone hexacetonide into the affected glenohumeral joint using the posterior approach with a 1.5-inch needle perpendicular to the scapular spine. Once per week for a maximum of 6 weeks or until no symptoms. An additional 19 ml of lidocaine 0.5% was injected for distension	*Steroid injection:* As for combined intervention except no injection of lidocaine for distension			Analgesic use (details not specified)

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Tveita 2008[36] RCT *Country, setting and treatment provider:* Norway; hospital	*Inclusion criteria:* Limitation of passive movement in the glenohumeral joint compared with the unaffected side, >30° for at least two of forward flexion, abduction or external rotation; patients with previous FS in opposite shoulder accepted even if difference between sides was <30°; pain in predominantly one shoulder lasting >3 months and <2 years; age >18 years or >70 years *Exclusion criteria:* Patients who could not comply with range of movement measurement procedures; diabetes mellitus; trauma to shoulder in the previous 6 months that required hospital care; serious mental illness; various contraindications to injections; patients currently taking corticosteroid tablets; reduction of glenohumeral range for reasons other than 'classic' adhesive capsulitis *Method of diagnosis:* Clinical history and radiography *Terminology used:* Adhesive capsulitis	*Age (years), mean (SD):* Steroid injection: 52 (7); hydrodilatation: 51 (6) *Female:* 59% *Any participants with diabetes?* No	*Duration of FS at baseline (months), mean (SD):* Steroid injection: 7 (4); hydrodilatation: 7 (4) *Stage of FS at baseline:* NR *Previous treatments for FS:* At baseline: patients undergoing physiotherapy $n=13$ (8 in steroid injection group, 5 in hydrodilatation group); patients taking analgesics daily $n=20$ (9 in steroid injection group, 11 in hydrodilatation group) *Participants with secondary FS:* None reported

Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise
Arthrographic distension + steroid: Dilatation with a corticosteroid, a contrast agent, local anaesthetic and saline necessary for dilatation and rupturing of the joint capsule. Injections were performed as for the corticosteroid group, except that the 4 ml of contrast medium, 2 ml of triamcinolone acetonide, 4 ml of local anaesthetic and 10 ml of saline were injected slowly into the joint. When resistance was met the injection was halted for a while and then continued. The capsule would usually rupture in the wall of the subscapular recess or sometimes in the wall of the bicipital or axillary recess, which was recorded as a loss of resistance, and contrast leakage was identified by fluoroscopy. If rupture had not occurred, more Ulravist/Marcain was injected until rupture. Three injections with 2-week intervals were given. The steps of the dilatation procedure were documented with repeat radiography examinations	*Steroid injection:* The Kaye–Schneider technique was used to perform arthrograms. Patients were supine and a mark was made with a pen on the glenohumeral joint space at about the junction of its middle and lower third using image-intensified fluoroscopy. The joint was punctured by a needle (22-gauge intramuscular needle); 3–4 ml of contrast medium (iopromide, Ultravist 300, Schering AG), 2 ml of triamcinolone acetonide (Kenacort, 10 mg/ml) and 3–4 ml of bupivacaine hydrochloride (Marcain, 5 mg/ml) were injected slowly. The position of the needle was checked frequently using fluoroscopy. Three injections with 2-week intervals were given. The steps of the injection were documented with repeat radiography examinations			Pain medication organised by the patients' primary care physicians Patients were allowed to proceed with their current physiotherapy programme; no patients were prescribed new physiotherapy programmes during the study

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

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Appendix 6.7 Capsular release

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Austgulen 2007[87] Case series *Country, setting and treatment provider:* Norway; Bergen Surgical Hospital; one surgeon performed surgery	*Inclusion criteria:* Patients with primary FS and stiffness typical of FS. Physiotherapy must have been tried previously without a satisfactory result *Exclusion criteria:* Secondary causes of FS (e.g. trauma) excluded *Method of diagnosis:* Diagnosis of FS was confirmed during anaesthesia; limited outward rotation of $<20°$ and $<45°$ in abduction with a fixed scapula *Terminology used:* FS	*Age (years), average (range):* 53 (34 to 71) *Female:* 67% *Any participants with diabetes?* Yes. $n=11$ with diabetes	*Duration of FS at baseline (months), average (range):* 13 (3 to 60 months) *Stage of FS at baseline:* NR *Previous treatments for FS:* Physiotherapy *Participants with secondary FS:* None reported

Intervention	Concomitant treatment and details of home exercise
Arthroscopic capsular and ligament release and PT: Surgery was performed using intravenous anaesthesia with addition of local infiltration. Patients were operated on in a beach chair position. Shoulder arthroscopy was performed using normal technique, with access to the shoulder joint from behind and surgical instruments entered in front in the rotator interval. The rotator interval was cleaned and the entire frontal capsule and glenohumeral ligament and coracohumeral ligament were split from the bicep tendon to 6 o'clock. Both capsules and ligaments were split with Acufex Upbiter Scissor punch. The subacromial space was inspected and adherences were loosened. The space and displacement were evaluated. Where spaces were narrow subacromial decompression was performed until it was possible to outwardly rotate the shoulder to maximum and abduct to 180°. All patients received aggressive rehabilitation with a physiotherapist from the first day after surgery *Home exercise*	NSAIDs and other pain relief given as needed. Oxycodone was given sometimes postoperatively. Patients received 40-mg bupivacaine injections into shoulder joints and cold packs pre- and postoperatively *Home exercise:* All did home exercises every day and performed stretches at home every day

Study	Inclusion/exclusion criteria and diagnosis of FS	Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
Chen 2002[88] Case series *Country, setting and treatment provider:* Taiwan; Kaohisiung Medical University Hospital	*Inclusion criteria:* Basic criteria for definition of idiopathic FS *Exclusion criteria:* NR *Method of diagnosis:* Idiopathic FS diagnosed using history, physical examination, X-ray and arthrography *Terminology used:* FS	*Age (years), range:* 32 to 79 *Female:* 75% *Any participants with diabetes?* Unclear/NR	*Duration of FS at baseline (months), average (range):* 8 (3 months to 4 years) *Stage of FS at baseline:* NR *Previous treatments for FS:* Participants had not responded to conservative treatment of at least 12 weeks' duration *Participants with secondary FS:* No

Intervention	Concomitant treatment and details of home exercise
Arthroscopic brisement (distension, debride, release) followed by gentle manipulation and PT: Distension was first undertaken to allow insertion of the arthroscope. The synovium was removed by arthroscopic shaver or vaporisation. The authors state that an attempt should be made to resect the areas of synovitis in the axillary pouch. In stage 3 disease residual synovial thickening or fibrotic changes are seen but the hypervascular appearance has resolved. The sheet of capsular tissue was debrided carefully. On removal of the arthroscopic instruments, a gentle manipulation was performed. The arm was elevated in the scapular plane (which was usually associated with audible popping of the contracted capsule) and then externally rotated and then internally rotated at varying degrees of abduction. This was done with gradual pressure and stopped if unyielding resistance was met. Repetition of these steps led to tearing of the capsular structures. The arm was then kept in the abduction–external rotation position for 2 days during which the patient was confined to bed. Passive and active exercise of the shoulder was then allowed, with a rehabilitation programme at the hospital rehabilitation facility (further details of the procedure are provided in the paper)	NR

FS, frozen shoulder; NR, not reported; PT, physiotherapy.

Appendix 7

Data extraction tables

Appendix 7.1 Steroid injection

Study: Bal 2008[68]

Outcome: Pain (pain at night) measured using VAS 0–100 mm

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*	
Steroid injection	Baseline	40 (42 shoulders)	77.5	20.0	
Placebo injection		40 (40 shoulders)	70.0	40.0	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	–36.5	25.1	0.07
Placebo injection		24 shoulders	–26.5	25.1	
Steroid injection	12 weeks	42 shoulders	–53.1	27.8	0.552
Placebo injection		24 shoulders	–51.7	28.1	

Outcome: Pain (pain on activity) measured using SPADI 5-item pain subscale

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*	
Steroid injection	Baseline	40 (42 shoulders)	71	39.7	
Placebo injection		40 (40 shoulders)	66	25.0	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	–30.1	22.1	0.041
Placebo injection		24 shoulders	–19	17.6	
Steroid injection	12 weeks	42 shoulders	–42.4	25.5	0.684
Placebo injection		24 shoulders	–44.8	19.4	

a All interventions received concomitant home exercise.
b *p*-value for between-group differences.

Study: Bal 2008[68]

Outcome: Function and disability measured using UCLA Shoulder scale

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*
Steroid injection	Baseline	40 (42 shoulders)	Baseline data not reported	
Placebo injection		40 (40 shoulders)		

Intervention[a]	*Time point*	*No. analysed*	*Median*	*IQR*
Steroid injection	2 weeks	42 shoulders	26.5	4.5
Placebo injection		24 shoulders	23	6.5
Steroid injection	12 weeks	42 shoulders	32.5	6.2
Placebo injection		24 shoulders	31.5	7.7

Outcome: Function and disability measured using SPADI total score

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*
Steroid injection	Baseline	40 (42 shoulders)	69.4	40.5
Placebo injection		40 (40 shoulders)	70.5	25.6

Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	–30.9	19.9	0.047
Placebo injection		24 shoulders	–20.2	15	
Steroid injection	12 weeks	42 shoulders	–44.4	24	0.407
Placebo injection		24 shoulders	–48.2	16.3	

Outcome: Function and disability measured using SPADI 8-item disability subscale

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*
Steroid injection	Baseline	40 (42 shoulders)	63.4	38.1
Placebo injection		40 (40 shoulders)	70.5	24.8

Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	–28.8	21.2	0.301
Placebo injection		24 shoulders	–23.1	17.8	
Steroid injection	12 weeks	42 shoulders	–42.2	26.3	0.156
Placebo injection		24 shoulders	–49.8	18.8	

a All interventions received concomitant home exercise.
b *p*-value for between-group differences.

Study: Bal 2008[68]

Outcome: Range of movement (°) – passive abduction

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*	
Steroid injection	Baseline	40 (42 shoulders)	107.5	41.2	
Placebo injection		40 (40 shoulders)	90	27.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	36.5	27.1	0.033
Placebo injection		24 shoulders	18.7	26.8	
Steroid injection	12 weeks	42 shoulders	57.8	27.9	0.639
Placebo injection		24 shoulders	54.2	29.1	

Outcome: Range of movement (°) – passive external rotation

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*	
Steroid injection	Baseline	40 (42 shoulders)	50	31.2	
Placebo injection		40 (40 shoulders)	40	17.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	18.4	16.3	0.173
Placebo injection		24 shoulders	12.9	13.4	
Steroid injection	12 weeks	42 shoulders	27.4	19.5	0.421
Placebo injection		24 shoulders	31.2	20.1	

Outcome: Range of movement (°) – passive internal rotation

Intervention[a]	*Time point*	*No. randomised*	*Median*	*IQR*	
Steroid injection	Baseline	40 (42 shoulders)	55	25.0	
Placebo injection		40 (40 shoulders)	47.5	10.0	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[b]
Steroid injection	2 weeks	42 shoulders	16.5	19.1	0.088
Placebo injection		24 shoulders	9.8	14.9	
Steroid injection	12 weeks	42 shoulders	25.7	19.1	0.693
Placebo injection		24 shoulders	54.2	29.1	

a All interventions received concomitant home exercise.
b *p*-value for between-group differences.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included passive forward flexion.

Study: Bal 2008[68]

Outcome: Quality of life

Not reported

Study: Bal 2008[68]

Outcome: Other

Not reported

Study: Bal 2008[68]

Outcome: Adverse events

No side effects were noted during the drug or exercise therapy sessions

Study: Carette 2003[35]

Outcome: Pain (pain overall) measured using SPADI 5-item pain subscale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection + PT	Baseline	21	69.0	17.1
Steroid injection		23	70.2	16.4
PT + placebo injection		26	65.4	19.7
Placebo injection		23	69.1	18.3
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*
Steroid injection + PT	6 weeks	21	–48.7	5.9
Steroid injection		23	–39.1	5.6
PT + placebo injection		26	–21.8	5.3
Placebo injection		23	–17.3	5.6
Steroid injection + PT	3 months	21	–52.1	5.9
Steroid injection		23	–48.1	5.6
PT + placebo injection		26	–38.1	5.3
Placebo injection		23	–30.1	5.6
Steroid injection + PT	6 months	21	–52.8	5.9
Steroid injection		23	–54.9	5.6
PT + placebo injection		26	–43.8	5.3
Placebo injection		23	–36.4	5.6
Steroid injection + PT	12 months	21	–48.4	5.9
Steroid injection		23	–52.6	5.6
PT + placebo injection		26	–46.1	5.3
Placebo injection		23	–46.0	5.6

Outcome: Pain (pain overall) measured using SPADI 5-item pain subscale – calculated values[b]

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*[c]
Steroid injection + PT	3 months	21	–52.1	13.1
Steroid injection		23	–48.1	13.1
PT + placebo injection		26	–38.1	13.1
Placebo injection		23	–30.1	13.1

PT, physiotherapy.

a All interventions received concomitant home exercise.

b Mean final values were calculated and SDs calculated for data closest to 3 months only.

c Average SD across all interventions for that outcome measured using the same instrument.

Study: Carette 2003[35]

Outcome: Function and disability measured using SPADI total score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	66.4	15.5	
Steroid injection		23	66.6	17.6	
PT + placebo injection		26	61.5	16.5	
Placebo injection		23	67.3	17.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	–46.5	5.3	24.3
Steroid injection		23	–36.7	5.1	24.5
PT + placebo injection		26	–22.2	4.8	24.5
Placebo injection		23	–18.9	5.1	24.5
Steroid injection + PT	3 months	21	–50.4	5.3	24.3
Steroid injection		23	–45.5	5.1	24.5
PT + placebo injection		26	–37.9	4.8	24.5
Placebo injection		23	–29.4	5.1	24.5
Steroid injection + PT	6 months	21	–52.5	5.3	24.3
Steroid injection		23	–51.3	5.1	24.5
PT + placebo injection		26	–43.1	4.8	24.5
Placebo injection		23	–38.4	5.1	24.5
Steroid injection + PT	12 months	21	–48.3	5.3	24.3
Steroid injection		23	–50.1	5.1	24.5
PT + placebo injection		26	–45.5	4.8	24.5
Placebo injection		23	–47.2	5.1	24.5

Outcome: Function and disability measured using SPADI 8-item disability subscale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	63.8	16.9	
Steroid injection		23	63	20.6	
PT + placebo injection		26	57.6	17.3	
Placebo injection		23	65.5	19.3	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	–44.3	5.2	23.8
Steroid injection		23	–34.2	5	24.0
PT + placebo injection		26	–22.7	4.7	24.0
Placebo injection		23	–20.4	4.9	23.5
Steroid injection + PT	3 months	21	–48.7	5.2	23.8
Steroid injection		23	–43	5	24.0
PT + placebo injection		26	–37.7	4.7	24.0
Placebo injection		23	–28.7	4.9	23.5
Steroid injection + PT	6 months	21	–52.1	5.2	23.8
Steroid injection		23	–47.6	5	24.0
PT + placebo injection		26	–42.3	4.7	24.0
Placebo injection		23	–40.5	4.9	23.5
Steroid injection + PT	12 months	21	–48.1	5.2	23.8
Steroid injection		23	–47.6	5	24.0
PT + placebo injection		26	–45	4.7	24.0
Placebo injection		23	–48.4	4.9	23.5

PT, physiotherapy.

a All interventions received concomitant home exercise.

b Average SD across all interventions for that outcome measured using the same instrument.

Study: Carette 2003[35]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	57.5	11.8	
Steroid injection		23	58.2	10.4	
PT + placebo injection		26	57.1	9.8	
Placebo injection		23	56.7	14.4	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	21	3	13.7
Steroid injection		23	12.9	2.9	13.9
PT + placebo injection		26	9.7	2.7	13.8
Placebo injection		23	5.7	2.9	13.9
Steroid injection + PT	3 months	21	24.4	3	13.7
Steroid injection		23	20.4	2.9	13.9
PT + placebo injection		26	14	2.7	13.8
Placebo injection		23	8.1	2.9	13.9
Steroid injection + PT	6 months	21	27.3	3	13.7
Steroid injection		23	22.1	2.9	13.9
PT + placebo injection		26	19.4	2.7	13.8
Placebo injection		23	14.3	2.9	13.9
Steroid injection + PT	12 months	21	29.7	3	13.7
Steroid injection		23	22.8	2.9	13.9
PT + placebo injection		26	24.7	2.7	13.8
Placebo injection		23	24	2.9	13.9

Outcome: Range of movement – passive external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	7.9	11.6	
Steroid injection		23	15.1	14	
PT + placebo injection		26	14.9	14.1	
Placebo injection		23	17.9	18.3	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	26.5	3.6	16.5
Steroid injection		23	18.3	3.4	16.3
PT + placebo injection		26	9.6	3.2	16.3
Placebo injection		23	7.1	3.4	16.3
Steroid injection + PT	3 months	21	31	3.6	16.5
Steroid injection		23	25.5	3.4	16.3
PT + placebo injection		26	18	3.2	16.3
Placebo injection		23	13.4	3.4	16.3
Steroid injection + PT	6 months	21	34.1	3.6	16.5
Steroid injection		23	29.5	3.4	16.3
PT + placebo injection		26	23	3.2	16.3
Placebo injection		23	20.8	3.4	16.3
Steroid injection + PT	12 months	21	38	3.6	16.5
Steroid injection		23	30.8	3.4	16.3
PT + placebo injection		26	31.6	3.2	16.3
Placebo injection		23	30.4	3.4	16.3

Outcome: Range of movement – hand behind back (cm)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	34.1	10.4	
Steroid injection		23	34.7	13.1	
PT + placebo injection		26	37.2	10.9	
Placebo injection		23	34	11	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	–19.8	2.5	11.5
Steroid injection		23	–11.3	2.4	11.5
PT + placebo injection		26	–10.5	2.3	11.7
Placebo injection		23	–10.8	2.4	11.5
Steroid injection + PT	3 months	21	–21.8	2.5	11.5
Steroid injection		23	–15.8	2.4	11.5
PT + placebo injection		26	–15.9	2.3	11.7
Placebo injection		23	–14.7	2.4	11.5
Steroid injection + PT	6 months	21	–22.8	2.5	11.5
Steroid injection		23	–17.4	2.4	11.5
PT + placebo injection		26	–18.1	2.3	11.7
Placebo injection		23	–16.9	2.4	11.5
Steroid injection + PT	12 months	21	–22.7	2.5	11.5
Steroid injection		23	–18.4	2.4	11.5
PT + placebo injection		26	–21.3	2.3	11.7
Placebo injection		23	–21.2	2.4	11.5

PT, physiotherapy.
a All interventions received concomitant home exercise.
b Average SD across all interventions for that outcome.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included passive forward flexion.

Study: Carette 2003[35]

Outcome: Quality of life – SF-36 PCS

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	35.2	7.8	
Steroid injection		23	37.5	9.1	
PT + placebo injection		26	37.6	7.7	
Placebo injection		23	36.8	7.7	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	6.4	1.9	8.7
Steroid injection		23	4.4	1.9	9.1
PT + placebo injection		26	1.1	1.9	9.7
Placebo injection		23	2.5	1.9	9.1
Steroid injection + PT	3 months	21	8.6	1.9	8.7
Steroid injection		23	10.1	1.9	9.1
PT + placebo injection		26	6.4	1.9	9.7
Placebo injection		23	5	1.9	9.1
Steroid injection + PT	6 months	21	8.8	1.9	8.7
Steroid injection		23	10.1	1.9	9.1
PT + placebo injection		26	9.1	1.9	9.7
Placebo injection		23	6.8	1.9	9.1
Steroid injection + PT	12 months	21	11.5	1.9	8.7
Steroid injection		23	11.1	1.9	9.1
PT + placebo injection		26	9.4	1.9	9.7
Placebo injection		23	10.1	1.9	9.1

Outcome: Quality of life – SF-36 MCS

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Steroid injection + PT	Baseline	21	43.1	12.9	
Steroid injection		23	49.4	10.2	
PT + placebo injection		26	49.8	11.8	
Placebo injection		23	49	12.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SE*	*SD*[b]
Steroid injection + PT	6 weeks	21	5.7	2.3	10.5
Steroid injection		23	1.5	2.2	10.6
PT + placebo injection		26	2	2.2	11.2
Placebo injection		23	2.6	2.2	10.6
Steroid injection + PT	3 months	21	6.6	2.3	10.5
Steroid injection		23	2.2	2.2	10.6
PT + placebo injection		26	3.8	2.2	11.2
Placebo injection		23	1.2	2.2	10.6
Steroid injection + PT	6 months	21	9.2	2.3	10.5
Steroid injection		23	3.8	2.2	10.6
PT + placebo injection		26	1	2.2	11.2
Placebo injection		23	2.1	2.2	10.6
Steroid injection + PT	12 months	21	9.3	2.3	10.5
Steroid injection		23	3.5	2.2	10.6
PT + placebo injection		26	2.4	2.2	11.2
Placebo injection		23	3.2	2.2	10.6

PT, physiotherapy.

a All interventions received concomitant home exercise.

b Average SD across all interventions for that outcome measured using the same instrument.

Study: Carette 2003[35]

Outcome: Adverse events

Not reported

Study: Carette 2003[35]

Outcome: Other

Not reported

Study: Dacre 1989[67]

Outcome: Pain (pain at night, pain with active and passive movement, day pain) measured using 10-cm VAS scale[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*p-value*
Steroid injection + PT	Baseline	Unclear[b]	Baseline data not reported	
Steroid injection		Unclear[b]		
PT		Unclear[b]		
Intervention	*Time point*	*No. analysed*	*Mean*	*p-value*
Steroid injection + PT	6 weeks	20	Mean measures of pain improved by 57–86% at 6 months	All groups showed significant reduction in pain after 6 weeks ($p < 0.001$)
Steroid injection		22		
PT		20	Pain on active movement improved by means of between 5% and 58% after 6 weeks	
Steroid injection + PT	6 months	20	Mean measures of pain improved by 57–86% at 6 months	
Steroid injection		22		
PT		20	Pain on active movement improved by means of between 62% and 78% at 6 months in the three groups (not significant)	

PT, physiotherapy.
a Data reported graphically and described in text only briefly.
b Sixty-six participants were randomised; the number randomised to each arm was not reported.

Study: Dacre 1989[67]
Outcome: Function and disability
Not reported

Study: Dacre 1989[67]				
Outcome: Range of movement – complete shoulder abduction, glenohumeral abduction and external rotation				
Intervention	*Time point*	*No. randomised*	*Mean*	*p-value*
Steroid injection + PT	Baseline	(Unclear)[b]	Baseline data not reported	
Steroid injection		(Unclear)[b]		
PT		(Unclear)[b]		
Intervention	*Time point*	*No. analysed*	*Mean*	*p-value*
Steroid injection + PT	6 weeks	20	Mean measures of movement improved by between 11% and 31% at 6 weeks	
Steroid injection		22	Total abduction improved by means of between 10% and 11% after 6 weeks in the three groups (not significant)	$p > 0.05$
PT		20		
Steroid injection + PT	6 months	20	Mean measures of movement improved by between 10% and 34% at 6 months	
Steroid injection		22	Total abduction improved by means of between 15% and 23% at 6 months in the three groups	$p > 0.05$
PT		20		

PT, physiotherapy.
a Data reported graphically and described in text only briefly.
b Sixty-six participants were randomised; the number randomised to each arm was not reported.

Study: Dacre 1989[67]
Outcome: Quality of life
Not reported

Study: Dacre 1989[67]
Outcome: Other
Not reported

Study: Dacre 1989[67]
Outcome: Adverse events
Stated that no patients had adverse reactions

Study: Rizk 1991[42]

Outcome: Pain (pain overall) measured using 0–5 Likert scale (0 = no pain, 5 = extreme pain)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*		
Steroid injection (anterior approach) + PT	Baseline	16	3.88	NR		
Steroid injection (lateral approach) + PT		16	3.7	NR		
Two arms for placebo injection (anterior approach and lateral) + PT[b]		16	4.07	NR		
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*Combined mean*[c]	*SD*[d]	
Steroid injection (anterior approach) + PT	4 weeks	15	3.87	NA	NA	
Steroid injection (lateral approach) + PT		14	3.71			
Two arms for placebo injection (anterior approach and lateral) + PT[b]		15	3.93	NA	NA	
Steroid injection (anterior approach) + PT	11 weeks	15	3.47	3.417	1.557	
Steroid injection (lateral approach) + PT		14	3.36			
Two arms for placebo injection (anterior approach and lateral) + PT[b]		15	3.13	3.13	1.653	
Steroid injection (anterior approach) + PT	24 weeks	15	3.2	3.1034	1.742	
Steroid injection (lateral approach) + PT		14	3			
Two arms for placebo injection (anterior approach and lateral) + PT[b]		15	3	3	1.673	

NA, not applicable; NR, not reported; PT, physiotherapy.

a All interventions received concomitant home exercise.

b This was a four-arm trial for which there were two placebo arms – a placebo injection administered using an anterior approach, and a placebo injection administered using a lateral approach.. For the results of pain, the study authors presented results for both placebo arms combined.

c The means of the two arms containing steroid injection were combined for the analysis of the outcome of pain as the advisory group stated that accuracy of the injection rather than approach was important.

d SD imputed using R model.

Study: Rizk 1991[42]

Outcome: Function and disability

Not reported

Study: Rizk 1991[42]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	Baseline	16	72.7	NR
Steroid injection (lateral approach) + PT		16	76.1	NR
Placebo injection (anterior approach) + PT		8	71.9	NR
Placebo injection (lateral approach) + PT		8	72.5	NR
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	1 week	Unclear	72.8	NR
Steroid injection (lateral approach) + PT		Unclear	76.4	NR
Placebo injection (anterior approach) + PT		Unclear	71.9	NR
Placebo injection (lateral approach) + PT		Unclear	72.5	NR
Steroid injection (anterior approach) + PT	2 weeks	Unclear	72.9	NR
Steroid injection (lateral approach) + PT		Unclear	75.9	NR
Placebo injection (anterior approach) + PT		Unclear	72.1	NR
Placebo injection (lateral approach) + PT		Unclear	72.5	NR
Steroid injection (anterior approach) + PT	3 weeks	Unclear	72.9	NR
Steroid injection (lateral approach) + PT		Unclear	75.6	NR
Placebo injection (anterior approach) + PT		Unclear	72.3	NR
Placebo injection (lateral approach) + PT		Unclear	72.8	NR
Steroid injection (anterior approach) + PT	4 weeks	Unclear	73	NR
Steroid injection (lateral approach) + PT		Unclear	75.6	NR
Placebo injection (anterior approach) + PT		Unclear	72.6	NR
Placebo injection (lateral approach) + PT		Unclear	73.1	NR
Steroid injection (anterior approach) + PT	5 weeks	Unclear	73.9	NR
Steroid injection (lateral approach) + PT		Unclear	75.9	NR
Placebo injection (anterior approach) + PT		Unclear	72.8	NR
Placebo injection (lateral approach) + PT		Unclear	73.3	NR
Steroid injection (anterior approach) + PT	6 weeks	Unclear	73.9	NR
Steroid injection (lateral approach) + PT		Unclear	76.3	NR
Placebo injection (anterior approach) + PT		Unclear	73.1	NR
Placebo injection (lateral approach) + PT		Unclear	73.3	NR
Steroid injection (anterior approach) + PT	7 weeks	Unclear	74.4	NR
Steroid injection (lateral approach) + PT		Unclear	76.8	NR
Placebo injection (anterior approach) + PT		Unclear	73.3	NR
Placebo injection (lateral approach) + PT		Unclear	73.7	NR
Steroid injection (anterior approach) + PT	8 weeks	Unclear	75.3	NR
Steroid injection (lateral approach) + PT		Unclear	77.1	NR
Placebo injection (anterior approach) + PT		Unclear	74.2	NR
Placebo injection (lateral approach) + PT		Unclear	74.2	NR
Steroid injection (anterior approach) + PT	9 weeks	Unclear	75.8	NR
Steroid injection (lateral approach) + PT		Unclear	78.3	NR
Placebo injection (anterior approach) + PT		Unclear	74.2	NR
Placebo injection (lateral approach) + PT		Unclear	74.2	NR
Steroid injection (anterior approach) + PT	10 weeks	Unclear	75.9	NR
Steroid injection (lateral approach) + PT		Unclear	79.1	NR
Placebo injection (anterior approach) + PT		Unclear	74.4	NR
Placebo injection (lateral approach) + PT		Unclear	74.5	NR

Steroid injection (anterior approach) + PT	11 weeks	Unclear	76.1	NR
Steroid injection (lateral approach) + PT		Unclear	79.8	NR
Placebo injection (anterior approach) + PT		Unclear	74.5	NR
Placebo injection (lateral approach) + PT		Unclear	74.7	NR
Steroid injection (anterior approach) + PT	15 weeks	Unclear	77.5	NR
Steroid injection (lateral approach) + PT		Unclear	79.9	NR
Placebo injection (anterior approach) + PT		Unclear	74.8	NR
Placebo injection (lateral approach) + PT		Unclear	75.4	NR
Steroid injection (anterior approach) + PT	6 months	Unclear	78.4	NR
Steroid injection (lateral approach) + PT		Unclear	81.9	NR
Placebo injection (anterior approach) + PT		Unclear	76.6	NR
Placebo injection (lateral approach) + PT		Unclear	80.1	NR

Outcome: Range of movement – passive external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	Baseline	16	33.6	NR
Steroid injection (lateral approach) + PT		16	30.1	NR
Placebo injection (anterior approach) + PT		8	30.4	NR
Placebo injection (lateral approach) + PT		8	32.3	NR

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	1 week	Unclear	33.8	NR
Steroid injection (lateral approach) + PT		Unclear	30.1	NR
Placebo injection (anterior approach) + PT		Unclear	30.5	NR
Placebo injection (lateral approach) + PT		Unclear	32.2	NR
Steroid injection (anterior approach) + PT	2 weeks	Unclear	33.9	NR
Steroid injection (lateral approach) + PT		Unclear	30.2	NR
Placebo injection (anterior approach) + PT		Unclear	30.5	NR
Placebo injection (lateral approach) + PT		Unclear	32.3	NR
Steroid injection (anterior approach) + PT	3 weeks	Unclear	34	NR
Steroid injection (lateral approach) + PT		Unclear	30.1	NR
Placebo injection (anterior approach) + PT		Unclear	30.9	NR
Placebo injection (lateral approach) + PT		Unclear	32.3	NR
Steroid injection (anterior approach) + PT	4 weeks	Unclear	34.1	NR
Steroid injection (lateral approach) + PT		Unclear	30.1	NR
Placebo injection (anterior approach) + PT		Unclear	31.2	NR
Placebo injection (lateral approach) + PT		Unclear	32.3	NR
Steroid injection (anterior approach) + PT	5 weeks	Unclear	34.2	NR
Steroid injection (lateral approach) + PT		Unclear	30.6	NR
Placebo injection (anterior approach) + PT		Unclear	31.4	NR
Placebo injection (lateral approach) + PT		Unclear	32.8	NR
Steroid injection (anterior approach) + PT	6 weeks	Unclear	34.4	NR
Steroid injection (lateral approach) + PT		Unclear	31.1	NR
Placebo injection (anterior approach) + PT		Unclear	31.5	NR
Placebo injection (lateral approach) + PT		Unclear	32.8	NR
Steroid injection (anterior approach) + PT	7 weeks	Unclear	34.8	NR
Steroid injection (lateral approach) + PT		Unclear	31.9	NR
Placebo injection (anterior approach) + PT		Unclear	31.9	NR
Placebo injection (lateral approach) + PT		Unclear	33	NR

Steroid injection (anterior approach) + PT	8 weeks	Unclear	34.9	NR
Steroid injection (lateral approach) + PT		Unclear	33.2	NR
Placebo injection (anterior approach) + PT		Unclear	32.8	NR
Placebo injection (lateral approach) + PT		Unclear	33.4	NR
Steroid injection (anterior approach) + PT	9 weeks	Unclear	34.9	NR
Steroid injection (lateral approach) + PT		Unclear	33.9	NR
Placebo injection (anterior approach) + PT		Unclear	32.9	NR
Placebo injection (lateral approach) + PT		Unclear	33.3	NR
Steroid injection (anterior approach) + PT	10 weeks	Unclear	34.9	NR
Steroid injection (lateral approach) + PT		Unclear	34.8	NR
Placebo injection (anterior approach) + PT		Unclear	33.3	NR
Placebo injection (lateral approach) + PT		Unclear	33.3	NR
Steroid injection (anterior approach) + PT	11 weeks	Unclear	34.9	NR
Steroid injection (lateral approach) + PT		Unclear	36.7	NR
Placebo injection (anterior approach) + PT		Unclear	33.4	NR
Placebo injection (lateral approach) + PT		Unclear	33.3	NR
Steroid injection (anterior approach) + PT	15 weeks	Unclear	36.9	NR
Steroid injection (lateral approach) + PT		Unclear	37.3	NR
Placebo injection (anterior approach) + PT		Unclear	34.9	NR
Placebo injection (lateral approach) + PT		Unclear	34.2	NR
Steroid injection (anterior approach) + PT	6 months	Unclear	40.2	NR
Steroid injection (lateral approach) + PT		Unclear	41	NR
Placebo injection (anterior approach) + PT		Unclear	40.8	NR
Placebo injection (lateral approach) + PT		Unclear	39.9	NR

Outcome: Range of movement – passive internal rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	Baseline	16	24.8	NR
Steroid injection (lateral approach) + PT		16	25.2	NR
Placebo injection (anterior approach) + PT		8	24.9	NR
Placebo injection (lateral approach) + PT		8	24.3	NR

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Steroid injection (anterior approach) + PT	1 week	Unclear	24.9	NR
Steroid injection (lateral approach) + PT		Unclear	25.3	NR
Placebo injection (anterior approach) + PT		Unclear	24.8	NR
Placebo injection (lateral approach) + PT		Unclear	24.4	NR
Steroid injection (anterior approach) + PT	2 weeks	Unclear	24.9	NR
Steroid injection (lateral approach) + PT		Unclear	25.1	NR
Placebo injection (anterior approach) + PT		Unclear	24.7	NR
Placebo injection (lateral approach) + PT		Unclear	24.4	NR
Steroid injection (anterior approach) + PT	3 weeks	Unclear	24.9	NR
Steroid injection (lateral approach) + PT		Unclear	24.7	NR
Placebo injection (anterior approach) + PT		Unclear	24.7	NR
Placebo injection (lateral approach) + PT		Unclear	24.4	NR
Steroid injection (anterior approach) + PT	4 weeks	Unclear	24.9	NR
Steroid injection (lateral approach) + PT		Unclear	24.7	NR
Placebo injection (anterior approach) + PT		Unclear	24.7	NR
Placebo injection (lateral approach) + PT		Unclear	25.1	NR

Steroid injection (anterior approach) + PT	5 weeks	Unclear	25.1	NR
Steroid injection (lateral approach) + PT		Unclear	24.6	NR
Placebo injection (anterior approach) + PT		Unclear	25.1	NR
Placebo injection (lateral approach) + PT		Unclear	25.3	NR
Steroid injection (anterior approach) + PT	6 weeks	Unclear	25.3	NR
Steroid injection (lateral approach) + PT		Unclear	24.7	NR
Placebo injection (anterior approach) + PT		Unclear	25.1	NR
Placebo injection (lateral approach) + PT		Unclear	25.7	NR
Steroid injection (anterior approach) + PT	7 weeks	Unclear	25.8	NR
Steroid injection (lateral approach) + PT		Unclear	24.6	NR
Placebo injection (anterior approach) + PT		Unclear	25.2	NR
Placebo injection (lateral approach) + PT		Unclear	25.7	NR
Steroid injection (anterior approach) + PT	8 weeks	Unclear	26.1	NR
Steroid injection (lateral approach) + PT		Unclear	24.6	NR
Placebo injection (anterior approach) + PT		Unclear	25.3	NR
Placebo injection (lateral approach) + PT		Unclear	25.8	NR
Steroid injection (anterior approach) + PT	9 weeks	Unclear	26.1	NR
Steroid injection (lateral approach) + PT		Unclear	24.9	NR
Placebo injection (anterior approach) + PT		Unclear	25.6	NR
Placebo injection (lateral approach) + PT		Unclear	25.7	NR
Steroid injection (anterior approach) + PT	10 weeks	Unclear	26.1	NR
Steroid injection (lateral approach) + PT		Unclear	25.5	NR
Placebo injection (anterior approach) + PT		Unclear	25.8	NR
Placebo injection (lateral approach) + PT		Unclear	25.7	NR
Steroid injection (anterior approach) + PT	11 weeks	Unclear	26.1	NR
Steroid injection (lateral approach) + PT		Unclear	25.9	NR
Placebo injection (anterior approach) + PT		Unclear	26.1	NR
Placebo injection (lateral approach) + PT		Unclear	25.8	NR
Steroid injection (anterior approach) + PT	15 weeks	Unclear	28.7	NR
Steroid injection (lateral approach) + PT		Unclear	26.1	NR
Placebo injection (anterior approach) + PT		Unclear	26.7	NR
Placebo injection (lateral approach) + PT		Unclear	26.4	NR
Steroid injection (anterior approach) + PT	6 months	Unclear	32.4	NR
Steroid injection (lateral approach) + PT		Unclear	30.8	NR
Placebo injection (anterior approach) + PT		Unclear	31.8	NR
Placebo injection (lateral approach) + PT		Unclear	30.6	NR

NR, not reported, PT, physiotherapy.
a All interventions received concomitant home exercise.
Note: Other range of movement reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included passive flexion, passive extension, passive adduction and total range of movement (sum of shoulder motion in three planes: internal–external rotation, flexion–extension and adduction–abduction).

Study: Rizk 1991[42]

Outcome: Quality of life

Not reported

Study: Rizk 1991[42]

Outcome: Other

Not reported

Study: Rizk 1991[42]

Outcome: Adverse events

Study authors stated: 'No withdrawals due to adverse effects'

Study: Ryans 2005[41]

Outcome: Pain (daytime pain at rest) measured using 100-mm VAS

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection + PT	Baseline	20	31.2	21
Steroid injection		20	37.8	19.8
PT + placebo injection		20	45.8	24.7
Placebo injection		20	44.1	33.7
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Steroid injection + PT	6 weeks	17	–16.3	26.4
Steroid injection		17	–9.7	18.5
PT + placebo injection		20	–17.6	39.1
Placebo injection		17	–5.4	27.8
Steroid injection + PT	16 weeks	17	–16.1	24.4
Steroid injection		13	–9.8	24.7
PT + placebo injection		16	–29.3	33.7
Placebo injection		12	–24.5	34.2

Outcome: Pain (daytime pain at rest) measured using 100-mm VAS – calculated values

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*[b]
Steroid injection + PT	6 weeks	17	14.9	10.39
Steroid injection		17	28.1	10.39
PT + placebo injection		20	28.2	10.39
Placebo injection		17	38.7	10.39

PT, physiotherapy.

a All interventions received concomitant home exercise.

b Calculated from average SD across all interventions for that outcome measured using the same instrument.

Study: Ryans 2005[41]

Outcome: Function and disability, measured using UK SDQ/Croft score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection + PT	Baseline	20	13.6	4
Steroid injection		20	15.8	4.5
PT + placebo injection		20	14.9	4.8
Placebo injection		20	14.1	4.6

Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Steroid injection + PT	6 weeks	17	–7.8	5.7
Steroid injection		17	–6.1	6.4
PT + placebo injection		20	–3.5	4.9
Placebo injection		17	–3.1	3.4
Steroid injection + PT	16 weeks	17	–7.6	5.8
Steroid injection		13	–7.8	5.9
PT + placebo injection		16	–5.6	5.8
Placebo injection		12	–6.6	5.4

Outcome: Function and disability, self-assessed global function measured using 100-mm VAS

Intervention[a]	*Time point*	*Number randomised*	*Mean*	*SD*
Steroid injection + PT	Baseline	20	57.2	16.2
Steroid injection		20	65	17.2
PT + placebo injection		20	63.9	21.4
Placebo injection		20	62.7	26.9

Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Steroid injection + PT	6 weeks	17	–37.8	18.1
Steroid injection		17	–28.4	24.1
PT + placebo injection		20	–26.1	26.7
Placebo injection		17	–16.8	22
Steroid injection + PT	16 weeks	17	–39.2	25.8
Steroid injection		13	–35.6	26.9
PT + placebo injection		16	–42.7	29.4
Placebo injection		12	–40.7	26.7

PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Ryans 2005[41]

Outcome: Range of movement – passive external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Steroid injection + PT	Baseline	20	31.6	13.3
Steroid injection		20	31.7	14.1
PT + placebo injection		20	28.1	15
Placebo injection		20	26.7	10.3
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Steroid injection + PT	6 weeks	17	21	16.5
Steroid injection		17	14.3	15.2
PT + placebo injection		20	16.7	13.2
Placebo injection		17	6.6	13.2
Steroid injection + PT	16 weeks	17	19.7	19.7
Steroid injection		13	19.1	19.2
PT + placebo injection		16	18	14
Placebo injection		12	22.2	18.2

PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Ryans 2005[41]

Outcome: Quality of life – SF-36 domain score and HADS anxiety and HADS depression score

Baseline values reported only, therefore data not extracted

HADS, Hospital Anxiety and Depression Scale.

Study: Ryans 2005[41]

Outcome: Other

Not reported

Study: Ryans 2005[41]

Outcome: Adverse events

Not reported

Appendix 7.2 Sodium hyaluronate

Study: Calis 2006[66]

Outcome: Pain (pain overall) measured using VAS

Data provided in graphical format only. Text states that there was significant improvement in pain severity at 3 months within all treatment groups including no intervention group ($p < 0.001$). There was significantly greater improvement in the steroid group than in the placebo group ($p = 0.02$)

Study: Calis 2006[66]

Outcome: Function and disability measured using the Constant score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Sodium hyaluronate injection	Baseline	24 (27 shoulders)	50.1	8.9	
Steroid injection		25 (26 shoulders)	54.6	9.7	
PT		21 (22 shoulders)	55.3	9.4	
No intervention		20 (20 shoulders)	51.2	12.1	
Intervention[a]	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*
Sodium hyaluronate injection	15 days	24 (27 shoulders)	58.4	11	
Steroid injection		25 (26 shoulders)	66.5	11.6	
PT		21 (22 shoulders)	70.2	11.6	< 0.05[b]
No intervention		20 (20 shoulders)	57.9	11.5	
Sodium hyaluronate injection	3 months	24 (27 shoulders)	70.1	10.3	< 0.05[c]
Steroid injection		25 (26 shoulders)	70.3	9.9	< 0.05[d]
PT		21 (22 shoulders)	76.1	10.7	< 0.05[e]
No intervention		20 (20 shoulders)	61.2	10.8	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b *p*-value for difference between physical therapy and sodium hyaluronate, and between physical therapy and no intervention.
c *p*-value for difference between sodium hyaluronate and no intervention.
d *p*-value for difference between steroid and no intervention.
e *p*-value for difference between physical therapy and no intervention.

Study: Calis 2006[66]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Sodium hyaluronate injection	Baseline	24 (27 shoulders)	109.6	17.8	
Steroid injection		25 (26 shoulders)	117.8	23.6	
PT		21 (22 shoulders)	116.8	16.4	
No intervention		20 (20 shoulders)	114.2	22.1	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Sodium hyaluronate injection	15 days	24 (27 shoulders)	127.2	19	
Steroid injection		25 (26 shoulders)	135.1	23.4	
PT		21 (22 shoulders)	145.4	19.2	<0.05[b]
No intervention		20 (20 shoulders)	125	20.1	
Sodium hyaluronate injection	3 months	24 (27 shoulders)	145.9	21	
Steroid injection		25 (26 shoulders)	150.3	19.6	<0.05[c]
PT		21 (22 shoulders)	158.4	18.3	<0.05[d]
No intervention		20 (20 shoulders)	133.5	15.3	

Outcome: Range of movement – passive external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Sodium hyaluronate injection	Baseline	24 (27 shoulders)	43.7	10.5	
Steroid injection		25 (26 shoulders)	47.3	12.5	
PT		21 (22 shoulders)	50	10.6	
No intervention		20 (20 shoulders)	45.7	9	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Sodium hyaluronate injection	15 days	24 (27 shoulders)	52.9	10.7	
Steroid injection		25 (26 shoulders)	54.8	10.5	
PT		21 (22 shoulders)	63.8	11.7	<0.05[e]
No intervention		20 (20 shoulders)	52.7	9.3	
Sodium hyaluronate injection	3 months	24 (27 shoulders)	63.3	11.4	
Steroid injection		25 (26 shoulders)	63	10.8	
PT		21 (22 shoulders)	73.8	10.4	<0.05[e]
No intervention		20 (20 shoulders)	55	8.1	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b *p*-value for difference between physiotherapy and sodium hyaluronate, and between physical therapy and no intervention.
c *p*-value for difference between steroid and no intervention.
d *p*-value for difference between physiotherapy and no intervention.
e *p*-values for difference between physiotherapy and sodium hyaluronate, physical therapy and steroid, and physical therapy and no intervention.

Study: Calis 2006[66]

Outcome: Quality of life

Not reported

Study: Calis 2006[66]

Outcome: Other

Not reported

Study: Calis 2006[66]

Outcome: Adverse events

Not reported

Study: Rovetta 2008[68]

Outcome: Pain (pain on passive joint motion), measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*[a]	*SD*[b]	
Sodium hyaluronate + steroid injection + PT	Baseline	14	7.7	1	
Steroid injection + PT		16	7.6	1	
Intervention	*Time point*	*No. analysed*	*Mean*[a]	*SD*[b]	*p-value*[c]
Sodium hyaluronate + steroid injection + PT	6 months	14	6	1	< 0.0001
Steroid injection + PT		16	5.2	1	< 0.0001

PT, physiotherapy.
a Assumed to be a mean, although not explicitly stated in the paper.
b Assumed to be SD, although not explicitly stated in the paper.
c *p*-value for within-group change from baseline.

Study: Rovetta 2008[68]

Outcome: Function and disability

Not reported

Study: Rovetta 2008[68]

Outcome: Range of movement – abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*[a]	*SD*[b]	
Sodium hyaluronate + steroid injection + PT	Baseline	14	77.8	6	
Steroid injection + PT		16	76.5	56	
Intervention	*Time point*	*No. analysed*	*Mean*[a]	*SD*[b]	*p-value*[c]
Sodium hyaluronate + steroid injection + PT	6 months	14	95.5	31	< 0.01
Steroid injection + PT		16	98.7	30	< 0.05

Outcome: External rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*[a]	*SD*[b]	
Sodium hyaluronate + steroid injection + PT	Baseline	14	16.4	5	
Steroid injection + PT		16	12.2	3	
Intervention	*Time point*	*No. analysed*	*Mean*[a]	*SD*[b]	*p-value*[c]
Sodium hyaluronate + steroid injection + PT	6 months	14	38.5	21	< 0.001
Steroid injection + PT		16	37.8	19	< 0.001

Outcome: Range of movement – internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*[a]	*SD*[b]	
Sodium hyaluronate + steroid injection + PT	Baseline	14	25.7	7	
Steroid injection + PT		16	25.3	7	
Intervention	*Time point*	*No. analysed*	*Mean*[a]	*SD*[b]	*p-value*[c]
Sodium hyaluronate + steroid injection + PT	6 months	14	27.5	10	<0.001
Steroid injection + PT		16	51.2	18	<0.01

PT, physiotherapy.
a Assumed to be a mean, although not explicitly stated in the paper.
b Assumed to be SD, although not explicitly stated in the paper.
c *p*-value for within-group change from baseline.

Study: Rovetta 2008[68]

Outcome: Quality of Life

Not reported

Study: Rovetta 2008[68]

Outcome: Other

Joint capsule thickness was reported but data were not extracted as this was not an outcome of interest

Study: Rovetta 2008[68]

Outcome: Adverse events

Not reported

Study: Takagishi 1996[70]

Outcome: Pain (pain on activity), measured using VAS 0–10

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Sodium hyaluronate injection	Baseline	10	8	1.8
Steroid injection		10	7.2	2.1

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Sodium hyaluronate injection	5 weeks[a]	10	3.7	1.7
Steroid injection		10	4.2	2.7

Outcome: Pain (no. of patients experiencing pain at night)

Intervention	*Time point*	*No. randomised*	*No. of patients*
Sodium hyaluronate injection	Baseline	10	8
Steroid injection		10	9

Intervention	*Time point*	*No. analysed*	*No. of patients*
Sodium hyaluronate injection	5 weeks[a]	10	4
Steroid injection		10	0

Outcome: Pain (no. of patients experiencing daytime pain)

Intervention	*Time point*	*No. randomised*	*No. of patients*
Sodium hyaluronate + steroid injection + PT	Baseline	10	8
Steroid injection + PT		10	8

Intervention	*Time point*	*No. analysed*	*No. of patients*
Sodium hyaluronate + steroid injection + PT	5 weeks[a]	10	4
Steroid injection + PT		10	2

PT, physiotherapy.
a Data were reported in graphical format only for weeks 1, 2, 3 and 4.

Study: Takagishi 1996[70]

Outcome: Function and disability measured using activities of daily living (ADL) questionnaire[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Sodium hyaluronate injection	Baseline	10	5.35	1.83
Steroid injection		10	4.95	2.5

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value[b]*
Sodium hyaluronate injection	5 weeks[c]	10	NR	NR	$p < 0.08$
Steroid injection		10	NR	NR	$p < 0.05$

a ADL questionnaire: Are the following impossible (0 points), difficult (0.5 points) or possible (1 point): tie hair, tie belt behind back, reach hand to mouth, sleep on painful side, take things from side pocket, reach opposite shoulder blade, open and close a sliding door, reach for things in the cupboard above one's head, go to the toilet, put on a jacket.
b *p*-value for within-group change from baseline.
c Data were reported in graphical format only for weeks 1, 2, 3 and 4.

Study: Takagishi 1996[70]				
Outcome: Range of movement – external rotation (°)				
Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Sodium hyaluronate injection	Baseline	10	18	13.6
Steroid injection		10	22.5	24.4
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Sodium hyaluronate injection	5 weeks[a]	10	24	22
Steroid injection		10	26	22

a Data were reported in graphical format only for weeks 1, 2, 3 and 4.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included joint flexion.

Study: Takagishi 1996[70]
Outcome: Quality of life
Not reported

Study: Takagishi 1996[70]
Outcome: Other
Not reported

Study: Takagishi 1996[70]
Outcome: Adverse events
Not reported

Appendix 7.3 Physical therapy

Study: Diercks 2004[73]
Outcome: Pain
Not reported

Study: Diercks 2004[73]

Outcome: Function and disability measured using the Constant score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	32	29.97	8.46	
Supervised neglect		45	28.6	8.64	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
PT	3 months	32	39.5	8.45	0.000
Supervised neglect		45	55.87	14.26	
PT	6 months	32	47.91	7.51	0.000
Supervised neglect		45	63.31	15	
PT	9 months	32	54.59	7.89	0.000
Supervised neglect		45	69.96	15.44	
PT	12 months	32	58.97	8.79	0.000
Supervised neglect		45	76.71	13.6	
PT	15 months	32	65.06	11.12	0.000
Supervised neglect		45	81.2	13.45	
PT	18 months	32	70.69	12.47	0.000
Supervised neglect		45	86.82	14.41	
PT	21 months	32	76.75	14.41	0.001
Supervised neglect		45	87.8	12.8	
PT	24 months	32	79.56	16.09	0.004
Supervised neglect		45	88.78	11.26	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b *p*-value is for between-group difference.

Study: Diercks 2004[73]

Outcome: Range of movement – Constant score for external rotation

Intervention[a]	*Time point*	*No. randomised*	*Median*	*Range*	*p-value*
PT	Baseline	32	2	NR	NR
Supervised neglect		45	2	NR	
Intervention[a]	*Time point*	*No. analysed*	*Median*	*Range*	*p-value*
PT	24 months	32	10	NR	NR
Supervised neglect		45	8	NR	

NR, not reported; PT, physiotherapy.
a All interventions received concomitant home exercise.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included the range of movement part of the Constant score for forward elevation and lateral elevation.

Study: Diercks 2004[73]

Outcome: Quality of life

Not reported

Study: Diercks 2004[73]

Outcome: Other

Not reported

Study: Diercks 2004[73]

Outcome: Adverse events

Not reported

Study: Dogru 2008[51]

Outcome: Pain (pain overall) measured using SPADI 5-item pain subscale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	66.9	13.8	
Sham ultrasound + PT		25 (24[b])	57.7	18	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	40.1	18.6	0.37
Sham ultrasound + PT		24	35.6	13.7	
Ultrasound + PT	3 months	25	31	20	0.39
Sham ultrasound + PT		24	25.5	18.3	

Outcome: Pain (pain on activity) measured using 0–100 mm VAS

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	80.8	18.2	
Sham ultrasound + PT		25 (24[b])	78	18.4	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Ultrasound + PT	2 weeks	25	39.6	25.3	0.56
Sham ultrasound + PT		24	40.7	20.3	
Ultrasound + PT	3 months	25	24.8	29.9	0.83
Sham ultrasound + PT		24	23.6	25.5	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b One participant dropped out in the first week; all analysis and baseline data were based on 24 participants.
c *p*-value is for between-group difference.

Study: Dogru 2008[51]					
Outcome: Function and disability measured using SPADI total score					
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	66.6	14.6	
Sham ultrasound + PT		25 (24[b])	62.1	17.3	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	37	18.6	0.72
Sham ultrasound + PT		24	38.2	17.8	
Ultrasound + PT	3 months	25	29.5	21.6	0.5
Sham ultrasound + PT		24	26.4	19.6	
Outcome: Function and disability measured by SPADI 8-item disability subscale					
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	66.5	13.7	
Sham ultrasound + PT		25 (24[b])	63.1	13.8	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	38.6	17.4	1
Sham ultrasound + PT		24	38.1	15.9	
Ultrasound + PT	3 months	25	30	20.9	0.45
Sham ultrasound + PT		24	25.5	17.8	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b One participant dropped out in the first week; all analysis and baseline data were based on 24 participants.
c *p*-value is for between-group difference.

Study: Dogru 2008[51]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	101.4	20.9	
Sham ultrasound + PT		25 (24[b])	113.5	14.1	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	142.8	25.9	0.72
Sham ultrasound + PT		24	146	26.2	
Ultrasound + PT	3 months	25	147.8	30.1	0.98
Sham ultrasound + PT		24	148	26.5	

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	34.8	14.7	
Sham ultrasound + PT		25 (24[b])	55.8	17.2	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	25	58	0.004
Sham ultrasound + PT		24	24	71.3	
Ultrasound + PT	3 months	25	25	65.7	0.05
Sham ultrasound + PT		24	24	75.4	

Outcome: Range of movement – internal rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	29.2	15.7	
Sham ultrasound + PT		25 (24[b])	47.3	18.8	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	2 weeks	25	52.2	15.7	0.12
Sham ultrasound + PT		24	58.3	15.5	
Ultrasound + PT	3 months	25	57.4	13.8	0.21
Sham ultrasound + PT		24	60.9	15.3	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b One participant dropped out in the first week; all analysis and baseline data were based on 24 participants.
c *p*-value is for between-group difference.

Study: Dogru 2008[51]					
Outcome: Quality of life – SF-36 PCS					
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	38.9	7.9	
Sham ultrasound + PT		25 (24[b])	36.6	9.8	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	3 months	25	44.2	8.4	0.83
Sham ultrasound + PT		24	44.6	8.8	
Outcome: Quality of life – SF-36 MCS					
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Ultrasound + PT	Baseline	25	43.5	10.2	
Sham ultrasound + PT		25 (24[b])	42	7.7	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[c]
Ultrasound + PT	3 months	25	44.8	11.5	0.81
Sham ultrasound + PT		24	43.8	10.6	

PT, physiotherapy.
a All interventions received concomitant home exercise.
b One participant dropped out in the first week; all analysis and baseline data were based on 24 participants.
c *p*-value is for between-group difference.

Study: Dogru 2008[51]
Outcome: Other outcome
Not reported

Study: Dogru 2008[51]
Outcome: Adverse events
Not reported

Study: Dundar 2009[74]

Outcome: Pain (pain at rest) measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	5.44	1.51
Conventional PT		28	5.54	1.64
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	2.86	1.96
Conventional PT		28	4.11	2.03
Continuous passive motion	12 weeks	29	2.41	1.72
Conventional PT		28	3.76	1.91

Outcome: Pain (pain on movement) measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	6.34	1.99
Conventional PT		28	6.31	1.86
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	4.06	2.13
Conventional PT		28	4.93	1.87
Continuous passive motion	12 weeks	29	3.75	1.92
Conventional PT		28	4.65	1.65

Outcome: Pain (pain at night) measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	6.1	1.75
Conventional PT		28	6	1.69
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	2 weeks	29	3.91	2.61
Conventional PT		28	4.84	1.66
Continuous passive motion	12 weeks	29	3.74	2.14
Conventional PT		28	4.64	1.77

Outcome: Pain (pain overall) measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	5.96	2
Conventional PT		28	5.92	1.8
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	2 weeks	29	4.01	2.1
Conventional PT		28	4.58	1.28
Continuous passive motion	12 weeks	29	3.79	2.01
Conventional PT		28	4.39	1.82

PT, physiotherapy.

Study: Dundar 2009[74]				
Outcome: Function and disability measured by SPADI 8-item disability subscale				
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	5.78	1.7
PT		28	5.69	1.84
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	4.03	1.58
PT		28	4.29	1.91
Continuous passive motion	12 weeks	29	3.82	1.61
PT		28	3.99	1.84
Outcome: Function and disability measured by Constant score				
Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	58.86	9.54
PT		28	57.59	9.32
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	74.86	9.64
PT		28	70.54	9.38
Continuous passive motion	12 weeks	29	79.63	9.45
PT		28	76.26	9.45

PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Dundar 2009[74]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	106.86	24.5
PT		28	103.45	23.6
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	137.96	16.26
PT		28	127.67	26.66
Continuous passive motion	12 weeks	29	141.75	13.11
PT		28	137.33	15.31

Outcome: Range of movement – passive external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	48.8	21.3
PT		28	49.7	21.2
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	65.82	17.54
PT		28	64.9	21.52
Continuous passive motion	12 weeks	29	68.22	17.11
PT		28	68.98	14.22

Outcome: Range of movement – passive internal rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Continuous passive motion	Baseline	29	44.19	19.06
PT		28	45.02	19.1
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Continuous passive motion	4 weeks	29	62.89	19.96
PT		28	64.45	17.8
Continuous passive motion	12 weeks	29	66.27	17.14
PT		28	67.19	18.47

PT, physiotherapy.
a All interventions received concomitant home exercise.
Note: Other range of movement reported, which was not of relevance to this review and is therefore not presented in the data extraction table, was passive flexion.

Study: Dundar 2009[74]

Outcome: Quality of life

Not reported

Study: Dundar 2009[74]

Outcome: Other outcome

Not reported

Study: Dundar 2009[74]

Outcome: Adverse events

No side effects were observed during the study

Study: Leung 2007[75]

Outcome: Pain

Not reported

Study: Leung 2007[75]

Outcome: Function and disability measured by SPADI 8-item disability subscale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
SWD + stretching	Baseline	10	41.5	12.1	
HP + stretching		10	38.9	11.8	
No intervention		10	33.3	12.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
SWD + stretching	2 weeks	10	56.3	15	0.046
HP + stretching		10	54.2	15.4	
No intervention		10	45.3	11.2	
SWD + stretching	4 weeks	10	67.8	15.1	NR
HP + stretching		10	56.5	14.1	
No intervention		10	46.1	12.7	
SWD + stretching	8 weeks	10	71.3	19.3	NR
HP + stretching		10	57.8	16.3	
No intervention		10	53.8	16.5	

NR, not reported.
a All interventions received concomitant home exercise.
b *p*-value for between-group difference.

Study: Leung 2007[75]

Outcome: Range of movement – external rotation (arm by side) (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
SWD + stretching	Baseline	10	50.4	14.1	
HP + stretching		10	28.2	23.4	
No intervention		10	39.5	21.7	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
SWD + stretching	2 weeks	10	59.3	19.8	0.09
HP + stretching		10	27.6	18.7	
No intervention		10	39.5	20.6	
SWD + stretching	4 weeks	10	60.9	14.5	NR
HP + stretching		10	32.6	21.1	
No intervention		10	43.3	22.6	

SWD + stretching	8 weeks	10	62.1	11.5	NR
HP + stretching		10	32.6	21.7	
No intervention		10	41.1	23.2	

Outcome: Range of movement – external rotation (arm at 90° abduction)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
SWD + stretching	Baseline	10	51.6	18.2	
HP + stretching		10	26.7	26	
No intervention		10	42.5	18.7	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
SWD + stretching	2 weeks	10	57.8	22.7	0.021
HP + stretching		10	27	26.5	
No intervention		10	43.4	20.8	
SWD + stretching	4 weeks	10	59.6	19.3	NR
HP+ stretching		10	30.1	26.8	
No intervention		10	45.7	23.3	
SWD + stretching	8 weeks	10	60.6	11	NR
HP + stretching		10	30.5	24.4	
No intervention		10	49	27.2	

Outcome: Range of movement – hand behind back (cm)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
SWD + stretching	Baseline	10	12.3	4.8	NR
HP + stretching		10	24.9	11.5	
No intervention		10	16	9.6	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
SWD + stretching	2 weeks	10	7.2	6.1	0.004
HP + stretching		10	22.2	11.5	
No intervention		10	14.7	8.1	
SWD + stretching	4 weeks	10	7.6	5.7	NR
HP + stretching		10	18.5	8.9	
No intervention		10	14.7	8	
SWD + stretching	8 weeks	10	6	7.3	NR
HP + stretching		10	18.3	7.5	
No intervention		10	13	6.7	

HP, heat pack; NR, not reported.
a All interventions received concomitant home exercise.
b *p*-value for between-group difference.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included flexion and cross-body adduction.

Study: Leung 2007[75]

Outcome: Quality of life

Not reported

Study: Leung 2007[75]

Outcome: Other

Not reported

Study: Leung 2007[75]

Outcome: Adverse events

Not reported

Study: Maricar 1999[76]

Outcome: Pain

Not reported

Study: Maricar 1999[76]

Outcome: Function and disability

Not reported

Study: Maricar 1999[76]

Outcome: Range of movement – external rotation, internal rotation and hand behind back

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	54	NR	NR
Exercises			NR	NR

Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline, p-values*
PT	3, 5, 7 and 8 weeks	16	Both groups showed significant improvement in all shoulder range of movements ($p < 0.001$). There was no significant difference between groups at weeks 3, 5, 7 or 8
Exercises		16	

NR, not reported; PT, physiotherapy.
a All interventions received concomitant home exercise.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included total elevation through flexion and hand behind neck.

Study: Maricar 1999[76]

Outcome: Quality of life

Not reported

Study: Maricar 1999[76]

Outcome: Adverse events

Not reported

Study: Maricar 1999[76]

Outcome: Other outcome

Not reported

Study: Pajareya 2004[77]

Outcome: Pain (no. of analgesics tablets taken)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	61	Baseline data not reported	
No intervention (information only)		61		
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
PT	3 weeks	60	61.38	
No intervention (information only)		59	58.59	

PT, physiotherapy.

Study: Pajareya 2004[77]

Outcome: Function and disability measured by SPADI 8-item disability subscale

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	61 (60[a])	54.93	21.3
No intervention (information only)		61 (59[a])	50.6	16.6
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
PT	3 weeks	60	20.5	15.4
No intervention (information only)		59	11.9	14.2

Outcome: Function and disability measured by global rating of pain and disability

Intervention	*Time point*	*No. randomised*	*No shoulder complaint, n (%)*
PT	Baseline	61 (60[a])	0
No intervention (information only)		61 (59[a])	0
Intervention	*Time point*	*No. randomised*	*Some pain or limitation but does not interfere with everyday life, n (%)*
PT	Baseline	61 (60[a])	0
No intervention (information only)		61 (59[a])	0
Intervention	*Time point*	*No. randomised*	*Minimal inconvenience, n (%)*
PT	Baseline	61 (60[a])	9 (15%)
No intervention (information only)		61 (59[a])	12 (20.3%)
Intervention	*Time point*	*No. randomised*	*Moderate inconvenience, n (%)*
PT	Baseline	61 (60[a])	35 (58.3%)
No intervention (information only)		61 (59[a])	34 (57.6%)
Intervention	*Time point*	*No. randomised*	*Marked inconvenience, n (%)*
PT	Baseline	61 (60[a])	16 (26.7%)
No intervention (information only)		61 (59[a])	13 (22.3%)

PT, physiotherapy.
a All analyses and baseline data based on the number followed up at 3 weeks.

Study: Pajareya 2004[77]

Outcome: Range of movement – abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	61 (60[a])	121.9	27.8
No intervention (information only)		61 (59[a])	121.3	27.8
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
PT	3 weeks	60	21.9	21
No intervention (information only)		59	14.7	18.1

Outcome: Range of movement – external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	61 (60[a])	74.8	22.1
No intervention (information only)		61 (59[a])	75.3	16
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
PT	3 weeks	60	21.3	15.3
No intervention (information only)		59	18.3	15.4

Outcome: Range of movement – internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	61 (60[a])	41.2	10.6
No intervention (information only)		61 (59[a])	41.1	10.3
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
PT	3 weeks	60	6.3	7.7
No intervention (information only)		59	3	7

PT, physiotherapy.
a All analyses and baseline data based on the number followed up at 3 weeks.

Study: Pajareya 2004[77]

Outcome: Quality of life

Not reported

Study: Pajareya 2004[77]

Outcome: Adverse events

Patients were asked, 'Have the trial drugs and/or treatment programme upset you in any way?', and were examined for signs of echymosis or burn during range of movement evaluation

PT	***10 episodes of pain (in 4 patients) that persisted for > 2 hours after treatment***
No intervention (information only)	15 patients had gastrointestinal side effects (6 had severe dyspepsia and discontinued NSAIDs; 2 had severe oedema; 1 had severe headache that subsided with discontinuation of NSAIDs)

Study: Pajareya 2004[77]

Outcome: Other – treatment success

Intervention	*Time point*	*No. randomised*	*n (%) patients who had successful treatment*
PT	Baseline	61 (60[a])	NA
No intervention (information only)		61 (59[a])	NA
Intervention	*Time point*	*No. analysed*	*n (%) patients who had successful treatment*
PT	3 weeks	60	21 (35)
No intervention (information only)		59	11 (18.6)
PT	6 weeks	60	35 (61.4)
No intervention (information only)		59	21 (60.8)
PT	12 weeks	60	43 (76.8)
No intervention (information only)		59	31 (60.8)
PT	24 weeks	60	45 (80.4)
No intervention (information only)		59	42 (82.4)

Outcome: Other – satisfaction[b]

Intervention	*Time point*	*No. analysed*	*No. patients 'very satisfied'*
PT	3 weeks	60	5
No intervention (information only)		59	1
Intervention	*Time point*	*No. analysed*	*No. patients 'moderately satisfied'*
PT	3 weeks	60	7
No intervention (information only)		59	1
Intervention	*Time point*	*No. analysed*	*No. patients 'unsatisfied'*
PT	3 weeks	60	24
No intervention (information only)		59	13
Intervention	*Time point*	*No. analysed*	*No. patients 'very unsatisfied'*
PT	3 weeks	60	23
No intervention (information only)		59	45

NA, not applicable; PT, physiotherapy.

a All analyses and baseline data based on the number followed up at 3 weeks.

b There may be an error in these data as responses for the PT group add up to 59 and those for the control group add up to 60.

Study: Stergioulas 2008[16]

Outcome: Pain (pain overall) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Laser therapy	Baseline	37	70.90	8.51
Placebo laser		37	67.03	8.12

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Laser therapy	4 weeks	31	32.34	7.44
Placebo laser		32	51.15	8.22
Laser therapy	8 weeks	31	27.41	6.72
Placebo laser		32	40.18	7.99
Laser therapy	16 weeks	31	23.92	6.11
Placebo laser		32	36.6	7.09

Outcome: Pain (pain at night) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Laser therapy	Baseline	37	77.91	9.23
Placebo laser		37	72.39	8.86

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Laser therapy	4 weeks	31	41.42	7.69
Placebo laser		32	55.67	8.49
Laser therapy	8 weeks	31	24.18	6.56
Placebo laser		32	49.33	8.05
Laser therapy	16 weeks	31	19.38	5.77
Placebo laser		32	42.35	7.57

Outcome: Pain (pain on activity) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Laser therapy	Baseline	37	80.55	8.82
Placebo laser		37	73.66	8.74

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Laser therapy	4 weeks	31	45.57	8.27
Placebo laser		32	67.75	8.03
Laser therapy	8 weeks	31	30.82	6.88
Placebo laser		32	51.39	8.58
Laser therapy	16 weeks	31	22.54	6.02
Placebo laser		32	39.78	7.65

Study: Stergioulas 2008[16]

Outcome: Function and disability measured by SPADI total score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Laser	Baseline	37	65.78	13.23
Placebo laser		37	61.67	14.22

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Laser	4 weeks	31	36.57	11.31	< 0.05
Placebo laser		32	48.35	13.61	

Laser	8 weeks	31	25.73	10.72	< 0.01
Placebo laser		32	39.84	11.11	
Laser	16 weeks	31	19.92	10.04	< 0.01
Placebo laser		32	33.75	10.43	

Outcome: Function and disability measured by Croft score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Laser	Baseline	37	13.85	4.44	
Placebo laser		37	15.63	4.79	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Laser	4 weeks	31	7.69	4.03	< 0.05
Placebo laser		32	14.52	4.37	
Laser	8 weeks	31	6.93	3.87	< 0.05
Placebo laser		32	11.27	4.23	
Laser	16 weeks	31	5.52	4.00	< 0.005
Placebo laser		32	12.65	4.31	

Outcome: Function and disability measured by DASH score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Laser	Baseline	37	48.56	14.19	
Placebo laser		37	43.09	13.78	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Laser	4 weeks	31	26.67	10.44	NR
Placebo laser		32	27.35	11.39	
Laser	8 weeks	31	20.64	9.89	< 0.05
Placebo laser		32	29.88	10.78	
Laser	16 weeks	31	15.23	7.98	< 0.005
Placebo laser		32	25.74	11.45	

Outcome: Function and disability measured by HAQ score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Laser	Baseline	37	2.03	0.81	
Placebo laser		37	2.24	0.92	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Laser	4 weeks	31	1.43	0.72	< 0.001
Placebo laser		32	2.14	0.78	
Laser	8 weeks	31	1.27	0.56	< 0.005
Placebo laser		32	2.02	0.8	
Laser	16 weeks	31	1.23	0.54	NR
Placebo laser		32	1.54	0.77	

NR, not reported.
a All interventions received concomitant home exercise.
b *p*-value is for between-group difference.

Study: Stergioulas 2008[16]

Outcome: Range of movement – active abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Laser	Baseline	37	65.56	12.05
Placebo laser		37	59.37	10.89
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Laser	4 weeks	31	78.67	13.76
Placebo laser		32	69.68	12.87
Laser	8 weeks	31	81.94	13.71
Placebo laser		32	76.47	9.65
Laser	16 weeks	31	85.63	13.95
Placebo laser		32	80.43	13.58

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Laser	Baseline	37	31.52	9.53
Placebo laser		37	28.63	8.79
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Laser	4 weeks	31	35.33	9.91
Placebo laser		32	33.56	9.12
Laser	8 weeks	31	37.13	9.97
Placebo laser		32	35.08	9.44
Laser	16 weeks	31	42.72	10.05
Placebo laser		32	38.53	9.9

a All interventions received concomitant home exercise.
Note: Other range of movement reported, which was not of relevance to this review and is therefore not presented in the data extraction tables, was active flexion.

Study: Stergioulas 2008[16]

Outcome: Quality of life

Not reported

Study: Stergioulas 2008[16]

Outcome: Other

Not reported

Study: Stergioulas 2008[16]

Outcome: Adverse events

Authors stated no complications were reported

Study: Vermeulen 2006[40]

Outcome: Pain (pain at rest) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	28	15.0 to 65.0
LGMT		51	36	20.0 to 64.5

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*95% CI*
HGMT	3 months	49	–15	–5.9 to –24.0
LGMT		51	–22.1	–15.6 to –28.7
HGMT	6 months	49	–22.3	–32.1 to –12.4
LGMT		51	–24.3	–31.3 to –17.4
HGMT	12 months	49	–23.9	–31.7 to –16.0
LGMT		51	–23	–30.8 to –15.2

Pain (pain during movement) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	59	46.0 to 78.0
LGMT		51	62	37.5 to 77.0

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*95% CI*
HGMT	3 months	49	–26.9	–19.0 to –34.7
LGMT		51	–24.3	–16.1 to –32.5
HGMT	6 months	49	–31.4	–39.5 to –23.2
LGMT		51	–31.9	–39.2 to –24.5
HGMT	12 months	49	–39.2	–47.2 to –31.2
LGMT		51	–32.6	–41.4 to –23.8

Pain (pain at night) measured using VAS 0–100 mm

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	72	47.0 to 84.0
LGMT		51	63	31.0 to 78.5

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*95% CI*
HGMT	3 months	49	–31.3	–20.3 to –42.4
LGMT		51	–27.5	–19.0 to –35.9
HGMT	6 months	49	–38.8	–50.8 to –26.9
LGMT		51	–31.7	–40.1 to –23.4
HGMT	12 months	49	–43.7	–53.6 to –33.8
LGMT		51	–35.9	–44.4 to –27.4

Study: Vermeulen 2006[40]

Outcome: Function and disability measured using the shoulder rating questionnaire

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	37.5	28.7 to 47.0
LGMT		51	39.5	31.0 to 49.6

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]
HGMT	3 months	49	25.8	17.4
LGMT		51	23.4	15.1
HGMT	6 months	49	32.3	19.3
LGMT		51	27.8	15.6
HGMT	12 months	49	38.3	19.2
LGMT		51	31.7	17.6

Outcome: Function and disability measured using the shoulder disability questionnaire (Dutch version)

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	81.2	75.0 to 87.5
LGMT		51	81.2	71.9 to 93.7

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]
HGMT	3 months	49	–29.9	25.2
LGMT		51	–24.7	24.5
HGMT	6 months	49	–38.9	32.0
LGMT		51	–33.2	27.5
HGMT	12 months	49	–50.0	30.5
LGMT		51	–38.8	27.5

a Computed from 95% CIs.

Study: Vermeulen 2006[40]

Outcome: Range of movement – active abduction (°)

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	75	60.0 to 90.0
LGMT		51	75	67.5 to 85.0

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]
HGMT	3 months	49	46.3	33.0
LGMT		51	36.3	28.8
HGMT	6 months	49	55.8	37.1
LGMT		51	46.9	31.8
HGMT	12 months	49	72.9	31.5
LGMT		51	60.3	32.5

Outcome: Range of movement – active external rotation (°)

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*	
HGMT	Baseline	49	20	10.0 to 25.0	
LGMT		51	20	7.5 to 30.0	
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]	
HGMT	3 months	49	11.6	11.3	
LGMT		51	9.3	14.6	
HGMT	6 months	49	15.9	12.7	
LGMT		51	13.2	13.1	
HGMT	12 months	49	20.8	12.0	
LGMT		51	15.9	16.2	

Outcome: Range of movement – passive abduction (°)

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*	
HGMT	Baseline	49	85	70.0 to 95.0	
LGMT		51	85	80.0 to 95.0	
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]	*p-value*[b]
HGMT	3 months	49	47.9	31.7	<0.05
LGMT		51	34.8	26.5	
HGMT	6 months	49	57.1	34.5	
LGMT		51	46.1	29.4	
HGMT	12 months	49	72.4	29.4	<0.05
LGMT		51	59.9	29.1	

Outcome: Range of movement – passive external rotation (°)

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*	
HGMT	Baseline	49	20	10.0 to 30.0	
LGMT		51	20	12.5 to 35.0	
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]	*p-value*[b]
HGMT	3 months	49	13.1	11.8	
LGMT		51	11.7	13.1	
HGMT	6 months	49	16.8	13.4	
LGMT		51	12.7	12.4	
HGMT	12 months	49	21.9	14.3	<0.05
LGMT		51	15.4	17.4	

a Computed from 95% CIs.
b Determined by analysis of covariance with correction for baseline values.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included active forward flexion and passive forward flexion.

Study: Vermeulen 2006[40]

Outcome: Quality of life – SF-36 PCS

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	43.8	31.9 to 54.2
LGMT		51	45.1	36.3 to 57.5

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]
HGMT	3 months	49	14.2	16.0
LGMT		51	13.6	17.8
HGMT	6 months	49	19.2	18.8
LGMT		51	17.1	17.8
HGMT	12 months	49	23.2	21.9
LGMT		51	22.8	19.7

Outcome: Quality of life – SF-36 MCS

Intervention	*Time point*	*No. randomised*	*Median*	*IQR*
HGMT	Baseline	49	73.4	51.9 to 87.0
LGMT		51	73.2	51.9 to 83.5

Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*[a]
HGMT	3 months	49	8.6	17.1
LGMT		51	4.5	23.4
HGMT	6 months	49	8.2	20.4
LGMT		51	7.9	21.7
HGMT	12 months	49	7.7	20.4
LGMT		51	10.2	4.8

a Computed from 95% CIs.

Study: Vermeulen 2006[40]

Outcome: Other outcome

Not reported

Study: Vermeulen 2006[40]

Outcome: Adverse events

Not reported

Study: Yang 2007[78]

Outcome: Pain

Not reported

Study: Yang 2007[78]

Outcome: Function and disability measured using the Flexilevel Scale of Shoulder Function

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
ERM + MRM	Baseline	14	NR	NR
MWM + MRM		14	NR	NR
Intervention	*Time point*	*No. analysed*	*Mean % of change*	*SD*
ERM + MRM	6 weeks	14	19.9	8.1
MWM + MRM		13	17.25	12.2

NR, not reported.

Study: Yang 2007[78]

Outcome: Range of movement – external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
ERM + MRM	Baseline	14	NR	NR
MWM + MRM		14	NR	NR
Intervention	*Time point*	*No. analysed*	*Mean % of change*	*SD*
ERM + MRM	6 weeks	14	36.4	24.3
MWM + MRM		13	34.2	14.3

Outcome: Range of movement – internal rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
ERM + MRM	Baseline	14	NR	NR
MWM + MRM		14	NR	NR
Intervention	*Time point*	*No. analysed*	*Mean % of change*	*SD*
ERM + MRM	6 weeks	14	20.5	24.4
MWM + MRM		13	45.6	38.5

NR, not reported.
Note: The FASTRAK motion analysis system, arm elevation, scapular tipping and scapulohumeral rhythm were also reported.

Study: Yang 2007[78]

Outcome: Quality of life

Not reported

Study: Yang 2007[78]

Outcome: Other

Not reported

Study: Yang 2007[78]

Outcome: Adverse events

Not reported

Study: Yan 2005[72]

Outcome: Pain

Not reported

Study: Yan 2005[72]

Outcome: Function and disability

Not reported

Study: Yan 2005[72]

Outcome: Range of movement

Measures of interest not reported

Note: Arm bending towards the front of the shoulder, arm stretching towards the lower back and arm stretching of upper outside of the arm were reported.

Study: Yan 2005[72]

Outcome: Other – rate of improvement[a]

Intervention	*Time point*	*No. analysed*	*No. of patients with bad outcome*
Dumb-bell gymnastics	3 months	26	0
Barehanded exercises		28	7
Intervention	*Time point*	*No. analysed*	*No. of patients with average outcome*
Dumb-bell gymnastics	3 months	26	0
Barehanded exercises		28	16
Intervention	*Time point*	*No. analysed*	*No. of patients with good outcome*
Dumb-bell gymnastics	3 months	26	2
Barehanded exercises		28	5
Intervention	*Time point*	*No. analysed*	*No. of patients with excellent outcome*
Dumb-bell gymnastics	3 months	26	24
Barehanded exercises		28	0

a Rate of improvement: excellent (pain disappeared and normal function completely recovered), good (a little pain on movement and normal function partially recovered), average (some reduction in pain and improvement in range of movement), bad (no improvement in pain and no change in range of movement).

Study: Yan 2005[72]

Outcome: Quality of life

Not reported

Study: Yan 2005[72]

Outcome: Other

Not reported

Study: Yan 2005[72]

Outcome: Adverse events

Not reported

Study: Wies 2003[71]

Outcome: Pain

Not reported

Study: Wies 2003[71]

Outcome: Function and disability measured by SPADI total score

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	10	NR	NR	
Osteopathy technique		10	NR	NR	
Control		10	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[a]
PT	9 weeks	10	18.8	23.6	0.059
Osteopathy technique		10	38.7	22.5	
Control		10	22.8	18.2	

NR, not reported; PT, physiotherapy.
a *p*-value for between-group differences.

Study: Wies 2003[71]

Outcome – Range of movement – active abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	10	NR	NR	
Osteopathy technique		10	NR	NR	
Control		10	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*	*p-value*[a]
PT	9 weeks	10	39.6	35.8	NR
Osteopathy technique		10	46	23	
Control		10	0.8	39.5	

NR, not reported; PT, physiotherapy.
a *p*-value for between-group differences.

Study: Wies 2003[71]

Outcome: Quality of life

Not reported

Study: Wies 2003[71]

Outcome: Adverse events

Not reported

Study: Wies 2003[71]

Outcome: Other outcome

Not reported

Appendix 7.4 Acupuncture (with or without physical therapy)

Study: Cheing 2008[81]

Outcome: Pain (pain at moment) measured using VAS 0–10 cm

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Electroacupuncture	Baseline	25	6.5	2.1
Interferential electrotherapy		24	6.5	2
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Electroacupuncture	4 weeks	24	3.5	1.9
Interferential electrotherapy		23	3.4	1.9
Electroacupuncture	Approx. 2 months	24	3.1	2.2
Interferential electrotherapy		23	2.4	1.7
Electroacupuncture	Approx. 4 months	24	2.4	2.2
Interferential electrotherapy		23	2	1.5
Electroacupuncture	Approx. 7 months	24	1.7	2.3
Interferential electrotherapy		23	1.3	1.4

a All interventions received concomitant home exercise.

Study: Cheing 2008[81]

Outcome: Function and disability – Constant Murley Assessment Score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Electroacupuncture	Baseline	25	65.5	16.7
Interferential electrotherapy		24	59.6	15.4
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Electroacupuncture	4 weeks	24	86	8.2
Interferential electrotherapy		23	84.9	8.4
Electroacupuncture	Approx. 2 months	24	89.3	4.8
Interferential electrotherapy		23	92.1	5.9
Electroacupuncture	Approx. 4 months	24	93.3	6.0
Interferential electrotherapy		23	90.2	9.7
Electroacupuncture	Approx. 7 months	24	93.8	6.4
Interferential electrotherapy		23	95.5	4.1

a All interventions received concomitant home exercise.

Study: Cheing 2008[81]

Outcome: Range of movement

Not reported

Study: Cheing 2008[81]

Outcome: Quality of life

Not reported

Study: Cheing 2008[81]

Outcome: Other

Not reported

Study: Cheing 2008[81]

Outcome: Adverse events

Not reported

Study: Fang 2006[82]

Outcome: Pain (pain overall) measured using VAS (range and units of measurement unspecified)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Electroacupuncture[b]	Baseline	77[b]	7.03	1.33
Electroacupuncture[c]		97[c]	5.51	2.54
TENS[b]		88[b]	7.26	1.15
TENS[c]		98[c]	6.01	2.59
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*
Electroacupuncture[b]	Post treatment	77[b]	1.65	2.12
Electroacupuncture[c]		97[c]	2.31	2.11
TENS[b]		88[b]	2.28	2.4
TENS[c]		98[c]	2.65	2.06

a All interventions received concomitant home exercise.
b Patients had 'pre-adhesive capsulitis', which was defined as the patient having increased pain at night, but normal or slightly affected range of movement.
c Patients had adhesive capsulitis, which was defined as some reduction in pain but considerably reduced range of movement that can even affect activities of normal living.

Study: Fang 2006[82]

Outcome: Function and disability

Not reported

Study: Fang 2006[82]

Outcome: Range of movement

Not reported

Unspecified active range of movement was reported.

Study: Fang 2006[82]

Outcome: Quality of life

Not reported

Study: Fang 2006[82]

Outcome: Other – efficacy rate

Intervention[a]	*Time point*	*No. randomised*	*Mean*[b]	*SD*

Intervention[a]	*Time point*	*No. analysed*	*Cured (mean %)*	*SD*
Electroacupuncture[b]	Post treatment	77	32	41.6
Electroacupuncture[c]		97	11	11.3
TENS[b]		88	29	33
TENS[c]		98	9	9.2

Intervention[a]	*Time point*	*No. analysed*	*Large improvement (mean %)*	*SD*
Electroacupuncture[b]	Post treatment	77	27	35
Electroacupuncture[c]		97	49	50.5
TENS[b]		88	33	37.5
TENS[c]		98	40	40.8

Intervention[a]	*Time point*	*No. analysed*	*Improvement (mean %)*	*SD*
Electroacupuncture[b]	Post treatment	77	13	16.9
Electroacupuncture[c]		97	35	36.1
TENS[b]		88	23	26.1
TENS[c]		98	46	46.9

Intervention[a]	*Time point*	*No. analysed*	*No improvement (mean %)*	*SD*
Electroacupuncture[b]	Post treatment	77	5	6.5
Electroacupuncture[c]		97	2	2.1
TENS[b]		88	3	3.4
TENS[c]		98	3	3.1

Intervention[a]	*Time point*	*No. analysed*	*Total efficacy rate (%)*	*SD*
Electroacupuncture[b]	Post treatment	77	93.5	NR
Electroacupuncture[c]		97	97.9	NR
TENS[b]		88	96.6	NR
TENS[c]		98	96.9	NR

NR, not reported.

a All interventions received concomitant home exercise.

b Patients had 'pre-adhesive capsulitis', which was defined as the patient having increased pain at night, but normal or slightly affected range of movement.

c Patients had adhesive capsulitis, which was defined as some reduction in pain but considerably reduced range of movement that can even affect activities of normal living.

Study: Fang 2006[82]

Outcome: Adverse events

Not reported

Study: Ma 2006[83]

Outcome: Pain (pain at rest) measured using 0–10 numeric scale

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	1.8	NR	
Acupuncture		30	2.3	NR	
Acupuncture + PT		15	2.6	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	0.9	NR	0.0448
Acupuncture		30	0.8	NR	
Acupuncture + PT		15	0.9	NR	
PT	4 weeks	30	0.4	NR	0.0238
Acupuncture		30	0.7	NR	
Acupuncture + PT		15	0.7	NR	

Outcome: Pain (pain on activity) measured using 0–10 numeric scale

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	6.4	NR	
Acupuncture		30	7.3	NR	
Acupuncture + PT		15	7.4	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	5.4	NR	0.0398
Acupuncture		30	5.7	NR	
Acupuncture + PT		15	4.1	NR	
PT	4 weeks	30	3.7	NR	0.0137
Acupuncture		30	4.3	NR	
Acupuncture + PT		15	3.3	NR	

NR, not reported; PT, physiotherapy.
a *p*-value for between-group differences.

Study: Ma 2006[83]

Outcome: Range of movement – active abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	70.6	NR	
Acupuncture		30	88.8	NR	
Acupuncture + PT		15	79.5	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	84.9	NR	0.2645
Acupuncture		30	90.7	NR	
Acupuncture + PT		15	90.3	NR	
PT	4 weeks	30	98.3	NR	0.1634
Acupuncture		30	115.7	NR	
Acupuncture + PT		15	110.1	NR	

Outcome: Range of movement – active external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	15.9	NR	
Acupuncture		30	32.1	NR	
Acupuncture + PT		15	20.7	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	27.3	NR	0.5453
Acupuncture		30	42.7	NR	
Acupuncture + PT		15	30.1	NR	
PT	4 weeks	30	28.3	NR	0.0367
Acupuncture		30	43.2	NR	
Acupuncture + PT		15	36.1	NR	

Outcome: Range of movement – active internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	30	NR	
Acupuncture		30	41.3	NR	
Acupuncture + PT		15	33.6	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	37.5	NR	0.0656
Acupuncture		30	48.5	NR	
Acupuncture + PT		15	47.6	NR	
PT	4 weeks	30	43.9	NR	0.0656
Acupuncture		30	51.7	NR	
Acupuncture + PT		5	54.4	NR	

Outcome: Range of movement – passive abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
PT	Baseline	30	78	NR
Acupuncture		30	94.9	NR
Acupuncture + PT		15	84.8	NR

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	91.8	NR	0.0735
Acupuncture		30	99.2	NR	
Acupuncture + PT		15	100.5	NR	
PT	4 weeks	30	103.3	NR	0.0675
Acupuncture		30	120	NR	
Acupuncture + PT		15	110.7	NR	

Outcome: Range of movement – passive external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	23.4	NR	
Acupuncture		30	43.2	NR	
Acupuncture + PT		15	29.6	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	33.9	NR	0.6952
Acupuncture		30	55.8	NR	
Acupuncture + PT		15	34.2	NR	
PT	4 weeks	30	33.8	NR	0.8952
Acupuncture		30	52.3	NR	
Acupuncture + PT		15	38.5	NR	

Outcome: Range of movement – passive internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	37.6	NR	
Acupuncture		30	52.8	NR	
Acupuncture + PT		15	45.7	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	44.1	NR	0.7345
Acupuncture		30	59.3	NR	
Acupuncture + PT		15	50.1	NR	
PT	4 weeks	30	51.3	NR	0.4345
Acupuncture		30	56.3	NR	
Acupuncture + PT		15	59.2	NR	

NR, not reported; PT, physiotherapy.
a *p*-value for between-group differences.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included active flexion and extension and passive flexion and extension.

Study: Ma 2006[83]

Outcome: Quality of life – SF-36 physical function

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	74.8	NR	
Acupuncture		30	71.3	NR	
Acupuncture + PT		15	75.3	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[a]
PT	2 weeks	30	79	NR	0.3743
Acupuncture		30	78.8	NR	
Acupuncture + PT		15	86.9	NR	
PT	4 weeks	30	86.1	NR	0.8746
Acupuncture		30	81.3	NR	
Acupuncture + PT		15	86.9	NR	

Outcome: Quality of life – SF-36 role physical

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	20.2	NR	
Acupuncture		30	43.8	NR	
Acupuncture + PT		15	32.4	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	41.7	NR	0.7445
Acupuncture		30	56.7	NR	
Acupuncture + PT		15	45.7	NR	
PT	4 weeks	30	49.4	NR	0.0745
Acupuncture		30	45	NR	
Acupuncture + PT		15	45.1	NR	

Outcome: Quality of life – SF-36 bodily pain

Intervention	*Time point*	*No randomised*	*Mean*	*SD*	
PT	Baseline	30	46.3	NR	
Acupuncture		30	50.9	NR	
Acupuncture + PT		15	42.6	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	58.9	NR	0.4033
Acupuncture		30	54.7	NR	
Acupuncture + PT		15	50.4	NR	
PT	4 weeks	30	58.7	NR	0.6783
Acupuncture		30	66.3	NR	
Acupuncture + PT		15	53.4	NR	

Outcome: Quality of life – SF-36 general health

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	58.9	NR	
Acupuncture		30	50.5	NR	
Acupuncture + PT		15	54.3	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	63.3	NR	0.6004
Acupuncture		30	58.3	NR	
Acupuncture + PT		15	60.1	NR	

PT	4 weeks	30	73.3	NR	0.0604
Acupuncture		30	61.3	NR	
Acupuncture + PT		15	57.3	NR	

Outcome: Quality of life – SF-36 vitality

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	58.1	NR	
Acupuncture		30	53.4	NR	
Acupuncture + PT		15	52.4	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	69.3	NR	0.7894
Acupuncture		30	62.5	NR	
Acupuncture + PT		15	65.3	NR	
PT	4 weeks	30	73.3	NR	0.8894
Acupuncture		30	65	NR	
Acupuncture + PT		15	67.1	NR	

Outcome: Quality of life – SF-36 social functioning

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	83.9	NR	
Acupuncture		30	60.2	NR	
Acupuncture + PT		15	77.3	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	93.3	NR	0.0567
Acupuncture		30	68.8	NR	
Acupuncture + PT		15	89.5	NR	
PT	4 weeks	30	93.1	NR	0.0677
Acupuncture		30	75	NR	
Acupuncture + PT		15	83.5	NR	

Outcome: Quality of life – SF-36 role emotional

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	57	NR	
Acupuncture		30	75	NR	
Acupuncture + PT		15	70.4	NR	
Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	61.1	NR	0.3458
Acupuncture		30	77.8	NR	
Acupuncture + PT		15	75.8	NR	
PT	4 weeks	30	66.3	NR	0.0578
Acupuncture		30	78.6	NR	
Acupuncture + PT		15	79.3	NR	

Outcome: Quality of life – SF-36 mental health

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
PT	Baseline	30	62.6	NR	
Acupuncture		30	69	NR	
Acupuncture + PT		15	65	NR	

Intervention	*Time point*	*No. analysed*	*Final value mean*	*SD*	*p-value*[a]
PT	2 weeks	30	65.9	NR	0.061
Acupuncture		30	72.7	NR	
Acupuncture + PT		15	68.6	NR	
PT	4 weeks	30	66.9	NR	0.091
Acupuncture		30	73	NR	
Acupuncture + PT		15	69.1	NR	

NR, not reported; PT, physiotherapy.
a *p*-value for between-group differences.

Study: Ma 2006[83]

Outcome: Other

Not reported

Study: Ma 2006[83]

Outcome: Adverse events

Not reported

Appendix 7.5 Manipulation under anaesthesia

Study: Amir-us-Saqlain 2007[84]

Outcome: Pain

Not reported

Study: Amir-us-Saqlain 2007[84]

Outcome: Function and disability

Not reported

Study: Amir-us-Saqlain 2007[84]

Outcome: Range of movement – active abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	33.75	11.03	
MUA + steroid injection + PT		20 (17)[a]	29.71	13.05	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	151.81	13.19	0.00
MUA + steroid injection + PT		17	122.82	21.08	

Outcome: Range of movement – active external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	28.56	24.45	
MUA + steroid injection + PT		20 (17)[a]	33.53	22.96	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	83.38	6.61	0.213
MUA + steroid injection + PT		17	76.76	19.76	

Outcome: Range of movement – active internal rotation[c]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	1.00	0.00	
MUA + steroid injection + PT		20 (17)[a]	1.12	0.33	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	3.56	0.51	0.00
MUA + steroid injection + PT		17	2.65	0.7	

Outcome: Range of movement – passive abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	45.88	14.91	
MUA + steroid injection + PT		20 (17)[a]	40.18	17.01	

Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	160.25	12.1	0.00
MUA + steroid injection + PT		17	137.76	15.21	
Outcome: Range of movement – passive external rotation (°)					
Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	37	23.22	
MUA + steroid injection + PT		20 (17)[a]	41.47	23.77	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	91.25	6.45	0.200
MUA + steroid injection + PT		17	86.41	13.38	
Outcome: Range of movement – passive internal rotation[c]					
Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	Baseline	23 (16)[a]	1	0.00	
MUA + steroid injection + PT		20 (17)[a]	1.18	0.39	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection + manipulated extremity kept in abduction and external rotation + PT	12 weeks	16	3.88	0.34	0.00
MUA + steroid injection + PT		17	2.88	0.49	

PT, physiotherapy.
a Baseline data not reported for patients lost to follow-up.
b *p*-value for between-group difference.
c Internal rotation was measured by spinal level (the metric used was not explicitly stated in the paper, but appears to be cm).
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included active forward flexion and passive forward flexion.

Study: Amir-us-Saqlain 2007[84]

Outcome: Quality of life

Not reported

Study: Amir-us-Saqlain 2007[84]

Outcome: Other

Not reported

Study: Amir-us-Saqlain 2007[84]

Outcome: Adverse events

Not reported

Study: Jacobs 2009[85]

Outcome: Pain measured using 100-point VAS

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA	Baseline	28	Baseline data not reported		
Steroid + distension		25			
Intervention	*Time point*	*No. analysed*	*Mean regression coefficient*	*SE*	*p-value, 95% CI*
MUA	16 weeks	19	–2.77	0.33	Not significant,[b] –1.11 to 1.15
Steroid + distension		24	–2.75	0.42	

a Data presented graphically; only mean regression coefficients reported.
b Exact *p*-value not reported.

Study: Jacobs 2009[85]

Outcome: Function and disability measured by the Constant score[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA	Baseline	28	Baseline data not reported		
Steroid + distension		25			
Intervention	*Time point*	*No. analysed*	*Mean regression coefficient*	*SE*	*p-value,[b] 95% CI*
MUA	16 weeks	19	3.13	0.24	Not significant, –0.90 to 1.11
Steroid + distension		24	3.23	0.42	

a Data presented graphically.
b *p*-value is for between-group difference; only mean regression coefficients reported.

Study: Jacobs 2009[85]

Outcome: Range of movement

Not reported

Study: Jacobs 2009[85]

Outcome: Quality of life, SF-36 components (general health, bodily pain, physical role, emotional role, social functioning, bodily pain, vitality, mental health)[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
MUA	Baseline	28	Baseline data not reported	
Steroid + distension		25		

Intervention	*Time point*	*No. analysed*	*Results reported*	*p-value[b]*
MUA	24 months	19	All components of the SF-36 improved for all patients during the course of treatment. The physical role and bodily pain components showed the greatest improvement	Not significant
Steroid + distension		24		

a Data reported graphically and brief description in text only.
b *p*-value is for between-group difference.

Study: Jacobs 2009[85]

Outcome: Other

Not reported

Study: Jacobs 2009[85]

Outcome: Adverse events

Not reported

Study: Kivimaki 2007[39]

Outcome: Pain (pain intensity) measured using Likert 0–10 scale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT	Baseline	65	6.6	0.3
Home exercise		60	6.4	0.3

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*[b]
MUA + PT	6 weeks	55	4.9	NR
Home exercise		55	4.7	NR
MUA + PT	3 months	51	4.9	2.735
Home exercise		50	4.7	2.735
MUA + PT	6 months	38	2.0	NR
Home exercise		45	2.8	NR
MUA + PT	12 months	37	1.5	NR
Home exercise		42	2.2	NR

Outcome: Pain (pain intensity) measured using Likert 0–10 scale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA

Intervention[a]	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	0.2	–0.64 to 1.02
MUA + PT vs home exercise	3 months	101	0.2	–1.06 to 1.10
MUA + physical therapy vs home exercise	6 months	83	–0.8	–1.80 to 0.20
MUA + PT vs home exercise	12 months	79	–0.7	–1.80 to 0.40

NA, not applicable; NR, not reported; PT, physiotherapy.
a All interventions received concomitant home exercise.
b SD calculated from 95% CI of mean difference.

Study: Kivimaki 2007[39]

Outcome: Function and disability measured with a modified version of the SDQ

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA

Interventiona	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	4	–3.8 to 11.8
MUA + PT vs home exercise	3 months	101	0.3	–2.69 to 2.75
MUA + PT vs home exercise	6 months	83	–1.7	–5.3 to 1.9
MUA + PT vs home exercise	12 months	79	0	–3.2 to 3.2

NA, not applicable; PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Kivimaki 2007[39]

Outcome: Range of movement – passive abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA
Intervention[a]	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	10	–3.2 to 23.2
MUA + PT vs home exercise	3 months	101	9	–6 to 24
MUA + PT vs home exercise	6 months	83	9	–4 to 22
MUA + PT vs home exercise	12 months	79	7	–5 to 19

Outcome: Range of movement – passive internal rotation (cm)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA
Intervention[a]	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	4	–1 to 9
MUA + PT vs home exercise	3 months	101	–3	–7.4 to 2.4
MUA + PT vs home exercise	6 months	83	–2	–7.4 to 3.4
MUA + PT vs home exercise	12 months	79	–1	–4.1 to 6.1

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA
Intervention[a]	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	5	–2 to 12
MUA + PT vs home exercise	3 months	101	6	–3to 15
MUA + PT vs home exercise	6 months	83	6	–2 to 14
MUA + PT vs home exercise	12 months	79	4	–4.2 to 12.2

NA, not applicable; NR, not reported; PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Kivimaki 2007[39]

Outcome: Quality of life

Not reported

Study: Kivimaki 2007[39]

Outcome: Other – working ability

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
MUA + PT vs home exercise	Baseline	125	NA	NA
Intervention[a]	*Time point*	*No. analysed*	*Mean difference*	*95% CI*
MUA + PT vs home exercise	6 weeks	110	0.4	–4.2 to 1.8
MUA + PT vs home exercise	3 months	101	0	–0.8 to 0.8
MUA + PT vs home exercise	6 months	83	0.5	–0.6 to 1.6
MUA + PT vs home exercise	12 months	79	0.1	–0.8 to1.0

NA, not applicable; PT, physiotherapy.
a All interventions received concomitant home exercise.

Study: Kivimaki 2007[39]

Outcome: Adverse events

There were no major complications during manipulation

Study: Quraishi 2007[38]

Outcome: Pain (pain overall), unspecified VAS

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*Range*	*SD*
MUA + steroid injection	Baseline	17 (18 shoulders)	5.7	3.0–8.5	NR
Arthrographic distension		19 (20 shoulders)	6.1	4.0–10	NR
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*Range*	*SD*
MUA + steroid injection	2 months	15 (16 shoulders)	4.7	0–8.5	NR
Arthrographic distension		18 (18 shoulders)	2.4	0–8.0	NR
MUA + steroid injection	6 months	15 (16 shoulders)	2.7	0–9.0	0.64
Arthrographic distension		18 (18 shoulders)	1.7	0–7.0	0.64

NR, not reported.
a All interventions received concomitant home exercise.

Study: Quraishi 2007[38]

Outcome: Function and disability measured using the Constant score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*Range*	
MUA + steroid injection	Baseline	17 (18 shoulders)	36	26–66	
Arthrographic distension		19 (20 shoulders)	28.8	18–55	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*[b]	*p-value*[c]
MUA + steroid injection	2 months	15 (16 shoulders)	58.5	NA	
Arthrographic distension		18 (18 shoulders)	57.4	NA	
MUA + steroid injection	6 months	15 (16 shoulders)	59.5	0.24	0.02
Arthrographic distension		18 (18 shoulders)	65.9	0.24	

NA, not applicable.
a All interventions received concomitant home exercise.
b *p*-value at 6 months was used to compute SD.
c *p*-value for between-group difference.

Study: Quraishi 2007[38]

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
MUA + steroid injection	Baseline	17 (18 shoulders)	NR	NR	
Arthrographic distension		19 (20 shoulders)	NR	NR	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection	6 months	15 (16 shoulders)	NR	NR	0.13
Arthrographic distension		18 (18 shoulders)	NR	NR	

Outcome: Range of movement – internal rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	*p-value*
MUA + steroid injection	Baseline	17 (18 shoulders)	NR	NR	NR
Arthrographic distension		19 (20 shoulders)	NR	NR	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection	6 months	15 (16 shoulders)	NR	NR	0.48
Arthrographic distension		18 (18 shoulders)	NR	NR	

Outcome: Range of movement – abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	*p-value*
MUA + steroid injection	Baseline	17 (18 shoulders)	NR	NR	NR
Arthrographic distension		19 (20 shoulders)	NR	NR	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
MUA + steroid injection	6 months	15 (16 shoulders)	NR	NR	0.62
Arthrographic distension		18 (18 shoulders)	NR	NR	

NR, not reported.
a All interventions received concomitant home exercise.
b *p*-value for between-group difference.

Study: Quraishi 2007[38]
Outcome: Quality of life
Not reported

Study: Quraishi 2007[38]
Outcome: Other – satisfaction
94% of patients were satisfied or very satisfied after arthrographic distension compared with 81% after MUA

Study: Quraishi 2007[38]
Outcome: Adverse events
Not reported

Appendix 7.6 Distension

Study: Buchbinder 2004[43]

Outcome: Pain (pain overall) measured using Likert 0–10 scale

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	6.0	2.0
Placebo (arthrogram only)		21	5.7	2.1
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*[b]	*SD*
Arthrographic distension + steroid	3 weeks	25	2.5	2.5
Placebo (arthrogram only)		21	0.2	1.7
Arthrographic distension + steroid	6 weeks	25	2.4	2.7
Placebo (arthrogram only)		21	1.0	2.4
Arthrographic distension + steroid	12 weeks	25	3.1	2.4
Placebo (arthrogram only)		21	2.4	2.8

Outcome: Pain (pain overall) measured using Likert 0–10 scale – calculated values[c]

Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*[d]
Arthrographic distension + steroid	6 weeks	25	3.6	2.69
Placebo (arthrogram only)	6 weeks	21	4.7	2.73
Arthrographic distension + steroid	12 weeks	25	2.9	2.69
Placebo (arthrogram only)	12 weeks	21	3.3	2.73

a All interventions received concomitant home exercise.
b Baseline – follow-up value.
c Calculated for 6-week and 12-week data only.
d Imputed using R model.

Study: Buchbinder 2004[43]

Outcome: Function and disability measured using SPADI total score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	53.8	18.5
Placebo (arthrogram only)		21	55.7	22.6
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Arthrographic distension + steroid	3 weeks	25	21.8	19.3
Placebo (arthrogram only)		21	4.7	19.8
Arthrographic distension + steroid	6 weeks	25	21.6	23.0
Placebo (arthrogram only)		21	16.6	21.4
Arthrographic distension + steroid	12 weeks	25	28.7	23.9
Placebo (arthrogram only)		21	24.3	25.8

Outcome: Function and disability measured using the problem elicitation technique score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	172.6	48.2
Placebo (arthrogram only)		21	169.9	76.7
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Arthrographic distension + steroid	3 weeks	25	62.5	75.5
Placebo (arthrogram only)		21	8.7	29.0
Arthrographic distension + steroid	6 weeks	25	71.3	81
Placebo (arthrogram only)		21	25.3	34.4
Arthrographic distension + steroid	12 weeks	25	107.7	74.2
Placebo (arthrogram only)		21	53.3	70.3

a All interventions received concomitant home exercise.

Study: Buchbinder 2004[43]

Outcome: Range of movement – active abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	79.8	27.5
Placebo (arthrogram only)		21	72.9	21.2
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Arthrographic distension + steroid	3 weeks	25	20.2	30.2
Placebo (arthrogram only)		21	–0.2	22.5
Arthrographic distension + steroid	6 weeks	25	24.4	34.2
Placebo (arthrogram only)		21	15.5	26.1
Arthrographic distension + steroid	12 weeks	25	32.8	38.1
Placebo (arthrogram only)		21	28.3	29.9

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	41.7	20.2
Placebo (arthrogram only)		21	35.8	27.0
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Arthrographic distension + steroid	3 weeks	25	9.0	18.5
Placebo (arthrogram only)		21	3.2	19.9
Arthrographic distension + steroid	6 weeks	25	8.8	28.0
Placebo (arthrogram only)		21	15.3	33.7
Arthrographic distension + steroid	12 weeks	25	19.9	27.9
Placebo (arthrogram only)		21	17.8	29.2

Outcome: Range of movement – hand behind back (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	25	16.0	3.9
Placebo (arthrogram only)		21	16.7	4.2
Intervention[a]	*Time point*	*No. analysed*	*Mean change from baseline*	*SD*
Arthrographic distension + steroid	3 weeks	25	3.2	3.7
Placebo (arthrogram only)		21	–0.2	3.8
Arthrographic distension + steroid	6 weeks	25	3.4	4.3
Placebo (arthrogram only)		21	1.5	4.8
Arthrographic distension + steroid	12 weeks	25	4.2	4.4
Placebo (arthrogram only)		21	3.4	5.0

a All interventions received concomitant home exercise.
Note: Other range of movement reported, which was not of relevance to this review and is therefore not presented in the data extraction table, was shoulder flexion.

Study: Buchbinder 2004[43]

Outcome: Quality of life

Not reported

Study: Buchbinder 2004[43]

Outcome: Other

Not reported

Study: Buchbinder 2004[43]

Outcome: Adverse events

Total reported adverse events: arthrographic distension ($n=25$): 9 (36%), placebo ($n=21$): 1 (4%)
Pain associated with procedure: arthrographic distension ($n=25$): 4 (16%), placebo ($n=21$): 1 (4%)
Increased pain for up to 48 hours after procedure: arthrographic distension ($n=25$): 3 (12%), placebo ($n=21$): 1 (4%)
Claustrophobia at time of procedure: arthrographic distension ($n=25$): 1 (4%), placebo ($n=21$): 1 (4%)
Unsettled, anxious and hot: arthrographic distension ($n=25$): 0 (0%), placebo ($n=21$): 1 (4%)
Shoulder noisy (i.e. fluid noises): arthrographic distension ($n=25$): 1 (4%), placebo ($n=21$): 0 (0%)

Study: Gam 1998[86]

Outcome: Pain (pain at rest, pain on activity) measured using VAS 0–10 cm

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
Distension + steroid	Baseline	12	NR	NR	
Steroid injection		8	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Distension + steroid	Unclear	11	NR	NR	No difference between groups ($p=0.1$)
Steroid injection		7			

Outcome: Pain (analgesic consumption)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
Distension + steroid	Baseline	12	NR	NR	
Steroid injection		8	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Distension + steroid	Week 11	11	NR	NR	Analgesic consumption significantly lower in the distension group than in the steroid group ($p=0.008$)
Steroid injection		7			

NR, not reported.

Study: Gam 1998[86]

Outcome: Function and disability

Not reported

Study: Gam 1998[86]

Outcome: Range of movement – passive abduction[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
Distension + steroid	Baseline	12	NR	NR	
Steroid injection		8	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Distension + steroid	Unclear	11	There was no significant difference between groups (reported in the text)		NR
Steroid injection		7			

Outcome: Range of movement – passive external rotation[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*	
Distension + steroid	Baseline	12	NR	NR	
Steroid injection		8	NR	NR	
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*[b]
Distension + steroid	Unclear	11	There was a significant improvement with distension compared with steroid (reported in the text)		0.0007
Steroid injection		7			

a Graphical data only presented (for number achieving four levels of improvement).
b *p*-value for between-group difference.
Note: Other range of movements reported, which were not of relevance to this review and are therefore not presented in the data extraction tables, included passive flexion and extension.

Study: Gam 1998[86]

Outcome: Quality of life

Not reported

Study: Gam 1998[86]

Outcome: Other

Not reported

Study: Gam 1998[86]

Outcome: Adverse events

Two cases of unacceptable pain (dropouts)

Study: Tveita 2008[36]

Outcome: Pain

Not reported

Study: Tveita 2008[36]

Outcome: Function and disability measured using SPADI total score[a]

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	63	20
Steroid injection		39	59	20
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	26	19
Steroid injection		39	20	17

a Data were adjusted for baseline differences.

Study: Tveita 2008[36]

Outcome: Range of movement – active abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	57	21
Steroid injection		39	55	20
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	83	37
Steroid injection		39	86	34

Outcome: Range of movement – active external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	23	15
Steroid injection		39	22	16
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	37	17
Steroid injection		39	39	20

Outcome: Range of movement – active internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	46	15
Steroid injection		39	45	16
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	66	18
Steroid injection		39	68	17

Outcome: Range of movement – passive abduction (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	31	11
Steroid injection		39	31	11
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	46	13
Steroid injection		39	12	17

Outcome: Range of movement – passive external rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	19	13
Steroid injection		39	16	14
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	29	16
Steroid injection		39	27	17

Outcome: Range of movement – passive internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthrographic distension + steroid	Baseline	37	34	14
Steroid injection		39	32	13
Intervention	*Time point*	*No. analysed*	*Mean*	*SD*
Arthrographic distension + steroid	6 weeks after last injection	37	48	15
Steroid injection		39	45	12

Study: Tveita 2008[36]

Outcome: Quality of life

Not reported

Study: Tveita 2008[36]

Outcome: Other

Not reported

Study: Tveita 2008[36]

Outcome: Adverse events

Injections reported as very painful: distension: $n=5$, steroid: $n=6$

Other possible side effects reported: distension: $n=14$, steroid: $n=20$

Complaints of flushing or disturbances in heat regulation: distension: $n=9$, steroid: $n=13$

Minor loss of sensation and motor control loss in affected arm: distension: $n=2$; steroid: $n=2$

Loss of sleep, nausea or dizziness: number and treatment group unspecified

Glenohumeral joint infection: treatment group unspecified: $n=1$

Appendix 7.7 Capsular release

Study: Austgulen 2007[87]

Outcome: Pain

Not reported

Study: Austgulen 2007[87]

Outcome: Function and disability measured using the Oxford Shoulder score

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	41	75	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	18.4	7.3	< 0.001

Outcome: Function and disability measured using a telephone questionnaire (ability to work)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	2.4	2.6	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	7.4	2.5	< 0.001

Outcome: Function and disability measured using a telephone questionnaire (physical activity)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	2.3	2.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	7.4	2.4	< 0.001

Outcome: Function and disability measured using a telephone questionnaire (sleep at night)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	1.7	2.5	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	7.2	2.6	< 0.001

PT, physiotherapy.
a All patients received concomitant home exercise.
b Average follow-up was 10 months (range 3 to 29 months).

Study: Austgulen 2007[87]

Outcome: Range of movement – abduction (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	34	8	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	154	37	< 0.001

Outcome: Range of movement – external rotation (°)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	3	5	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	39	23	< 0.001

PT, physiotherapy.
a All patients received concomitant home exercise.
b Average follow-up was 10 months (range 3 to 29 months).
Note: Other range of movement reported, which was not of relevance to this review and is therefore not presented in the data extraction tables, was flexion.

Study: Austgulen 2007[87]

Outcome: Quality of life

Not reported

Study: Austgulen 2007[87]

Outcome: Adverse events

Two patients had FS again and had repeat surgery. No deep infections, nerve damage or other complications reported

Study: Austgulen 2007[87]

Outcome: Other (satisfaction, 10-point scale)

Intervention[a]	*Time point*	*No. randomised*	*Mean*	*SD*	
Arthroscopic capsular release and PT	Baseline	66 (70 shoulders)	NR	NR	
Intervention[a]	*Time point*	*No. analysed*	*Mean*	*SD*	*p-value*
Arthroscopic capsular release and PT	Postoperatively[b]	Unclear	8.6	1.6	NR

FS, frozen shoulder; PT, physiotherapy.
a All patients received concomitant home exercise.
b Average follow-up was 10 months (range 3 to 29 months).

Study: Chen 2002[88]

Outcome: Pain (reduction of pain)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*[a]
Arthroscopic capsular release + manipulation + PT	Baseline	183 (186 shoulders)	NR	NR

Intervention	*Time point*	*No. analysed*	*Description of results provided in paper*
Arthroscopic capsular release + PT	Within 1 months	Unclear	Half of patients had pain relief within 1 month whether in motion or not
Arthroscopic capsular release + PT	After 3 months		All except eight shoulders were pain free in any direction of shoulder movement

NR, not reported; PT, physiotherapy.

Study: Chen 2002[88]

Outcome: Function and disability measured using a modified version of the ASES score

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*[a]
Arthroscopic capsular release + manipulation + PT	Baseline	183 (186 shoulders)	41	13

Intervention	*Time point*	*No. analysed*	*Mean improvement*	*SD*[a]	*p-value*
Arthroscopic capsular release + PT	Postoperatively[b]	Unclear	87	11	< 0.005

PT, physiotherapy.
a Not specified but assumed to be SD.
b Average follow-up was 23 months (range 5 to 6 years).

Study: Chen 2002[88]

Outcome: Range of movement – external rotation(°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthroscopic capsular release + manipulation + PT	Baseline	183 (186 shoulders)	NR	NR

Intervention	*Time point*	*No. analysed*	*Average gain in external rotation*	*SD*
Arthroscopic capsular release + PT	Postoperatively[a]	Unclear	35°	NR

Outcome: Range of movement – internal rotation (°)

Intervention	*Time point*	*No. randomised*	*Mean*	*SD*
Arthroscopic capsular release + manipulation + PT	Baseline	183 (186 shoulders)	NR	NR

Intervention	*Time point*	*No. analysed*	*Average gain in external rotation*	*SD*
Arthroscopic capsular release + PT	Postoperatively[a]	Unclear	30°	NR

NR, not reported; PT, physiotherapy.
a Average follow-up was 23 months (range 5 to 6 years).
Note: Other range of movement reported, which was not of relevance to this review and is therefore not presented in the data extraction tables, was gain in elevation.

Study: Chen 2002[88]
Outcome: Quality of life
Not reported

Study: Chen 2002[88]
Outcome: Other
Not reported

Study: Chen 2002[88]
Outcome: Adverse events
Complications occurred in only one patient (superficial wound infection)

Appendix 8

Study quality

Controlled trials

Study	No. of participants randomised stated	Method of randomisation	Allocation concealment	Comparability at baseline	Adjustment for baseline imbalance	Double blinded	Patients blinded	Outcome assessors blinded	Caregivers blinded	ITT analysis	Imbalances in dropouts	Imbalances in dropouts explained/adjusted for	Study powered
Amir-us-Saqlain 2007[84]	Y	U	U	Y[a]	N	U	U	U	N	U	N	NA	U/NR
Bal 2008[68]	Y	U	U	U	N	Y	Y	Y	N	N	Y	Y	U/NR
Buchbinder 2004[43]	Y	Y	Y	Y	NA	Y	Y	Y	N	Y	Y	Y	N
Calis 2006[66]	Y	U	U	Y	NA	N	U	Y	N	Y	N	NA	U/NR
Carette 2003[35]	Y	Y	Y	Y[b]	Y	U	U	Y	U	Y	Y	Y	N
Cheing 2008[81]	Y	U	U	Y	NA	Y	U	Y	U	N	N	NA	U/NR
Dacre 1989[67]	Y	U	U	U	N	N	N	Y	N	N	U	N	Y
Diercks 2004[73]	N	N	N	Y	NA	N	N	N	N	NA	N	NA	NA
Dogru 2008[51]	Y	U[c]	U	N	N	N	N	Y	U	N	N	NA	N[d]
Dundar 2009[74]	Y	U	U	Y	NA	N	U	U	U	U	N	NA	U
Fang 2006[82]	Y	U	U	U	N	N	Y	U	N	U	U	U	U/NR
Gam 1998[86]	Y	Y	U	U	NA	U	U	Y	U	N	N	NA	U/NR
Jacobs 2009[85]	Y	U	U	Y[e]	Y	N	N	U	N	N	U	U	N
Kivimaki 2007[39]	Y	Y	Y	Y	NA	N	N	Y	N	U	Y	N	Y[f]
Leung 2008[75]	Y	Y	U	Y	NA	N	N	Y	N	Y	N	NA	U/NR
Ma 2006[83]	Y	U[g]	U	Y	NA	N	N	U	N	U	U	NA	U/NR
Maricar 1999[76]	U[h]	U	U	Y	N	N	U	U	U	N	U	NA	U/NR
Pajareya 2004[77]	Y	N[i]	Y	Y	NA	N	U	U[j]	N	N	Y	N	N[d]

Study	No. of participants randomised stated	Method of randomisation	Allocation concealment	Comparability at baseline	Adjustment for baseline imbalance	Double blinded	Patients blinded	Outcome assessors blinded	Caregivers blinded	ITT analysis	Imbalances in dropouts	Imbalances in dropouts explained/adjusted for	Study powered
Quraishi 2007[38]	Y	Y	U	Y	NA	N	N	U	N	U	N	NA	U/NR
Rizk 1991[42]	Y	U	U	Y	NA	N	N	Y	N	N	N	NA	N
Rovetta 1998[69]	Y	U	U	Y	NA	N	U	U	U	U	U[k]	NA	U/NR
Ryans 2005[41]	Y	Y	U	Y	NA	N	Y	Y	N	N	Y	Y	N
Stergioulas 2008[16]	Y	Y	U[j]	Y	NA	Y	Y	Y	U	N	N	NA	U/NR
Takagishi 1996[70]	Y	U	U	U	U	U	U	U	U	U	U	NA	U/NR
Tveita 2008[36]	Y	Y	U	U[m]	Y[n]	N	N	N	N	Y	N	NA	N[o]
Vermeulen 2006[40]	Y	Y	U	Y	NA	N	N	Y	N	Y	N	NA	Y
Wies 2003[71]	N	U	U	U	NA	N	N	Y	N	U	U	U	U/NR
Yan 2005[72]	Y	U	U	U	NA	U	U	U	U	Y	N	NA	U/NR
Yang 2007[78]	Y	Y	Y	Y	NA	N	N	Y	U	Y	N	NA	N[d]

ITT, intention to treat; N, no; NA, not applicable; NR, not reported; U, unclear; Y, yes.

a Comparable for range of movement, unclear if comparable otherwise.
b Imbalance in gender between groups.
c Unclear whether assignment was truly random or occurred sequentially.
d Number in trial was less than that required by power calculation.
e Imbalance in number of women between study arms.
f Study was adequately powered at baseline but not at 12 months.
g States that patients were randomly assigned, but later states that the study was based on proactive quasi-experimental design.
h Unclear whether 54 or 32 were randomised.
i Envelopes not sequentially numbered.
j Assessor of adverse events blinded.
k Number at follow-up not reported.
l Unclear if envelopes sequentially numbered.
m Slightly higher proportion in steroid group had previous shoulder problems and were on sick leave.
n For SPADI.
o Authors judged that a smaller sample size would suffice because of use of regression analysis (expected to have greater power than *t*-test).

Observational studies

	Austgulen 2007[87]	Chen 2002[88]
Selection/eligibility criteria reported	Y	Y
Representativeness of population	P	U
Measure of variability	Y	N
Loss to follow-up reported/explained	U	U
≥90% follow-up	U	U
Patients recruited prospectively	Y	U
Patients recruited consecutively	U	U
Relevant prognostic factors reported	U	N

N, no; P, probably; U, unclear; Y, yes.

Appendix 9

WinBUGS code

```
#Random effects model for multi-arm trials (any number of arms)

model{
for(i in 1:N){

prec[i]<–1/var[i]

diff[i]~dnorm(delta[i],prec[i])                 # model
delta[i] ~ dnorm(md[i],taud[i])                 # trial-specific distributions
md[i] <- d[t[i]] – d[b[i]] + sw[i]              # mean of distributions
taud[i] <- tau *2*(nd[i])/(nd[i]+1)             #precision of distributions

dev[i]<-(diff[i]-delta[i])*(diff[i]-delta[i])/var[i]
}

#adjustment, multi-arm RCTs

sw[1] <–0
sw[2]<-((delta[1] – d[t[1]] + d[b[1]])*equals(s[1],s[2]))/nd[2]

for(i in 3:N){

sw[i] <- ((delta[i-1] – d[t[i-1]] + d[b[i-1]])*equals(s[i-1],s[i])+(delta[i-2]
– d[t[i-2]] + d[b[i-2]])*equals(s[i-2],s[i]))/nd[i]

}

sumdev<-sum(dev[])                              # residual deviance

d[1]<–0
for (k in 2:NT){d[k] ~ dnorm(0,.0001)}          # vague priors for basic parameters

sd~dunif(0,2)                                   # vague prior for random effects
standard deviation
tau<–1/pow(sd,2)
vr<–1/tau                                       # calculates the between study variance
}

list(
d=c(NA,0,0,0, 0,0,0),
sd=0.2
)
list(d=c(NA,0,1,0.5,0,0.2, 0.5), sd=0.05
)
```

list(N=10, NT=7)

diff[]	var[]	t[]	b[]	s[]	nd[]
–0.87879693	0.174990222	2	1	1	1
–1.267954169	0.194214046	4	1	1	2
–1.656708512	0.219586526	5	1	1	3
–0.988578325	0.235838433	2	1	2	1
–0.995913241	0.246188048	4	1	2	2
–2.236107822	0.334607203	5	1	2	3
–1.706048334	0.085049651	6	1	3	1
0.282054987	0.07987915	3	2	4	1
0.177	0.098	5	2	5	1
0.349115418	0.083611436	7	6	6	1

Appendix 10

Mixed-treatment comparison

Network 1: studies of any intervention (i.e. conservative and invasive) and any quality

Prior: Uniform (0, 0.8)

Comparator: placebo

		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	4	–1.71	–2.75 to –0.67[a]
Steroid + physiotherapy	6	–1.53	–2.41 to –0.75[a]
Electroacupuncture	7	1.36	–2.84 to 0.11
Physiotherapy + placebo	2	–1.22	–1.98 to –0.42[a]
Steroid	5	–1.15	–2.03 to –0.26[a]
Physiotherapy	3	–0.94	–2.20 to 0.38
MUA + physiotherapy	8	–0.87	–2.44 to 0.78
Sodium hyaluronate	10	–0.21	–1.13 to 0.69
Arthrographic distension + steroid	9	–0.15	–1.19 to 0.90

a Did not cross line of no effect.
Data points: 13; residual deviance: 12.72; τ^2 (between-study variance): 0.17 (95% CrI 0.0004 to 0.58).

Prior: Uniform (0, 2)

Comparator: placebo

		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	4	–1.71	–3.27 to –0.15[a]
Steroid + physiotherapy	6	–1.57	–2.80 to –0.53[a]
Electroacupuncture	7	–1.36	–3.55 to 0.84
Physiotherapy + placebo	2	–1.21	–2.27 to –0.06[a]
Steroid	5	–1.14	–2.31 to 0.05
Physiotherapy	3	–0.93	–2.78 to 1.02
MUA + physiotherapy	8	–0.85	–3.24 to 1.63
Sodium hyaluronate	10	–0.21	–1.71 to 1.27
Arthrographic distension + steroid	9	–0.15	–1.70 to 1.41

a Did not cross line of no effect.
Data points: 13; residual deviance: 12.59; τ^2 (between-study variance): 0.46 (95% CrI 0.0004 to 2.62).

Prior: Uniform (0, 10)

Comparator: placebo

		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	4	–1.70	–3.46 to 0.06
Steroid + physiotherapy	6	–1.57	–2.93 to –0.42[a]
Electroacupuncture	7	–1.35	–3.84 to 1.11
Physiotherapy + placebo	2	–1.21	–2.40 to 0.08
Steroid	5	–1.14	–2.44 to 0.19
Physiotherapy	3	–0.94	–3.03 to 1.26
MUA + physiotherapy	8	–0.86	–3.57 to 1.95
Sodium hyaluronate	10	–0.21	–1.90 to 1.46
Arthrographic distension + steroid	9	–0.14	–1.89 to 1.62

a Did not cross line of no effect.
Data points: 13; residual deviance: 12.69; τ^2 (between-study variance): 0.75 (95% CrI 0.0006 to 4.83).

Prior: Uniform (0, 15)

Comparator: placebo

		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	4	–1.71	–3.42 to 0.003
Steroid + physiotherapy	6	–1.57	–2.93 to –0.44[a]
Electroacupuncture	7	–1.36	–3.77 to 1.04
Physiotherapy + placebo	2	–1.22	–2.38 to 0.056
Steroid	5	–1.143	–2.45 to 0.17
Physiotherapy	3	–0.94	–2.98 to 1.24
MUA + physiotherapy	8	–0.86	–3.49 to 1.88
Sodium hyaluronate	10	–0.21	–1.87 to 1.45
Arthrographic distension + steroid	9	–0.15	–1.89 to 1.58

a Did not cross line of no effect.
Data points: 13; residual deviance: 12.69; τ^2 (between-study variance): 0.73 (95% CrI 0.0005 to 4.43).

Network 2: studies of any intervention that were of good or satisfactory quality (i.e. method of randomisation was adequate and outcome assessment was blinded)

There were five trials with data that could be used in the analysis of pain at or close to 3 months. Five interventions formed part of a connected network with placebo and the evidence was informed by four trials. The network is presented in *Figure 27*.

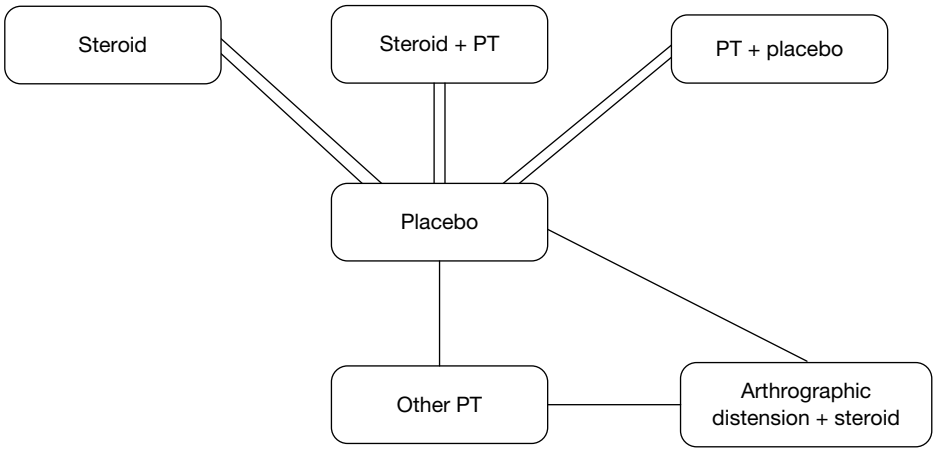

FIGURE 27 Network 2. PT, physical therapy.

Each line represents one comparison, for example there were two studies available for the comparison of steroid with placebo, and one study for the comparison of other physical therapy with placebo.

Prior: Uniform (0, 0.8)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.90	–2.79 to –1.02[a]
Physical therapy without mobilisation	5	–1.70	–2.66 to –0.75[a]
Steroid	3	–1.14	–1.98 to –0.31[a]
Physiotherapy + placebo	4	–0.93	–1.75 to –0.12[a]
Arthrographic distension + steroid	6	–0.15	–1.09 to 0.80

a Did not cross line of no effect.
Data points: 8; residual deviance: 6.30; τ^2 (between-study variance): 0.13 (95% CrI 0.0002 to 0.5585).

Prior: Uniform (0, 2)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.90	–3.06 to –0.78[a]
Physical therapy without mobilisation	5	–1.71	–3.15 to –0.29[a]
Steroid	3	–1.14	–2.24 to –0.03[a]
Physiotherapy + placebo	4	–0.92	–2.03 to 0.16
Arthrographic distension + steroid	6	–0.14	–1.59 to 1.29

a Did not cross line of no effect.
Data points: 8; residual deviance: 6.50; τ^2 (between-study variance): 0.38 (95% CrI 0.0002. to 2.55).

Prior: Uniform (0, 5)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.90	–3.24 to –0.61[a]
Physical therapy without mobilisation	5	–1.71	–3.43 to 0.002
Steroid	3	–1.14	–2.42 to 0.14
Physiotherapy + placebo	4	–0.93	–2.20 to 0.34
Arthrographic distension + steroid	6	–0.15	–1.87 to 1.55

a Did not cross line of no effect.
Data points: 8; residual deviance: 6.47; τ^2 (between-study variance): 0.70 (95% CrI 0.0002 to 5.8).

Prior: Uniform (0, 10)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.909	–3.31 to –0.54[a]
Physical therapy without mobilisation	5	–1.705	–3.54 to 0.12
Steroid	3	–1.15	–2.51 to 0.22
Physiotherapy + placebo	4	–0.9271	–2.9 to 0.43
Arthrographic distension + steroid	6	–0.1412	–1.97 to 1.70

a Did not cross line of no effect.
Data points: 8; residual deviance: 6.59; τ^2 (between-study variance): 1.02 (95% CrI 0.0002 to 7.47).

Network 3: studies of conservative treatments of any quality

There were six trials with data that could be used in the analysis of pain at or close to 3 months. Six interventions formed part of a connected network with placebo and the evidence was informed by six trials. The network is presented in *Figure 28*.

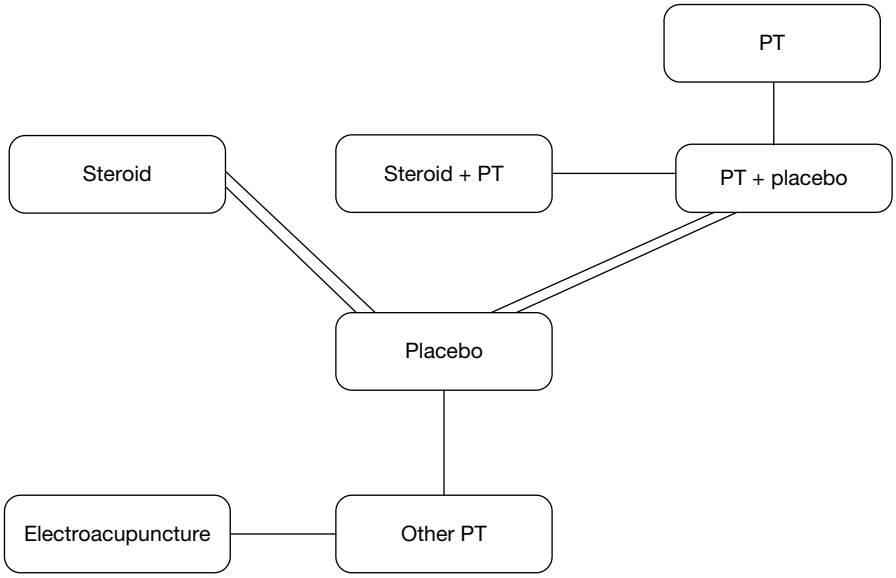

FIGURE 28 Network 3. PT, physical therapy.

Each line represents one comparison, for example there were two studies available for the comparison of steroid with placebo, and one study for the comparison of other physical therapy with placebo.

Prior: Uniform (0, 0.8)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	6	–1.71	–2.73 to –0.68[a]
Steroid + physiotherapy	5	–1.53	–2.40 to –0.75[a]
Electroacupuncture	7	–1.36	–2.81 to 0.092
Physiotherapy + placebo	2	–1.22	–1.98 to –0.42[a]
Steroid	4	–1.15	–2.02 to –0.27[a]
Physiotherapy	3	–0.94	–2.20 to 0.38

a Did not cross line of no effect.
Data points: 10; residual deviance: 9.70; τ^2 (between-study variance): 0.17 (95% CrI 0.0003 to 0.58).

Prior: Uniform (0, 2)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	6	–1.71	–3.24 to –0.19[a]
Steroid + physiotherapy	5	–1.56	–2.77 to –0.54[a]
Electroacupuncture	7	–1.36	–3.52 to 0.79
Physiotherapy + placebo	2	–1.21	–2.25 to –0.067[a]
Steroid	4	–1.14	–2.31 to 0.034
Physiotherapy	3	–0.92	–2.73 to 1.00

a Did not cross line of no effect.
Data points: 10; residual deviance: 9.64; τ^2 (between-study variance): 0.0.44 (95% CrI 0.0005 to 2.53).

Prior: Uniform (0, 5)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	6	–1.70	–3.43 to –0.002[a]
Steroid + physiotherapy	5	–1.58	–2.92 to –0.46[a]
Electroacupuncture	7	–1.35	–3.80 to 1.05
Physiotherapy + placebo	2	–1.21	–2.38 to 0.037
Steroid	4	–1.15	–2.43 to 0.14
Physiotherapy	3	–0.93	–2.98 to 1.21

a Did not cross line of no effect.
Data points: 10; residual deviance: 9.65; τ^2 (between-study variance): 0.65 (95% CrI 0.0004 to 4.29).

Prior: Uniform (0, 10)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Physical therapy without mobilisation	6	–1.70	–3.43 to 0.059
Steroid + physiotherapy	5	–1.57	–2.92 to –0.43[a]
Electroacupuncture	7	–1.35	–3.81 to 1.13
Physiotherapy + placebo	2	–1.21	–2.39 to 0.060
Steroid	4	–1.15	–2.45 to 0.15
Physiotherapy	3	–0.92	–2.99 to 1.25

a Did not cross line of no effect.
Data points: 10; residual deviance: 9.61; τ^2 (between-study variance): 0.72 (95% CrI 0.0004 to 4.54).

Network 4: studies of conservative treatments that were of good or satisfactory quality (i.e. method of randomisation was adequate and outcome assessment was blinded)

There were three trials with data that could be used in the analysis of pain at or close to 3 months. Four interventions formed part of a connected network with placebo and the evidence was informed by four trials. The network is presented in *Figure 29*.

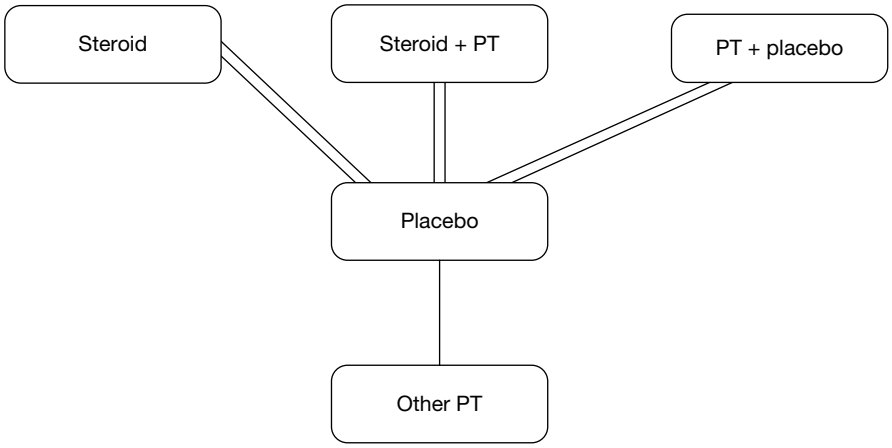

FIGURE 29 Network 4. PT, physical therapy.

Each line represents one comparison, for example there were two studies available for the comparison of steroid with placebo, and one study for the comparison of other physical therapy with placebo.

Prior: Uniform (0, 0.8)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.9	–2.79 to –1.02[a]
Physical therapy without mobilisation	5	–1.7	–2.66 to –0.76[a]
Steroid	3	–1.14	–1.97 to –0.31[a]
Physiotherapy + placebo	4	–0.94	–2.66 to –0.76[a]

PT, physical therapy.
a Did not cross line of no effect.
Data points: 7; residual deviance: 5.31; τ^2 (between-study variance): (95% CrI 0.0002 to 0.56).

Prior: Uniform (0, 2)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.911	–3.06 to –0.81[a]
Physical therapy without mobilisation	5	–1.706	–3.12 to –0.30[a]
Steroid	3	–1.146	–2.23 to –0.06[a]
Physiotherapy + placebo	4	–0.9251	–2.01 to 0.14

a Did not cross line of no effect.
Data points: 7; residual deviance: 5.44; τ^2 (between-study variance): 0.36 (95% CrI 0.0002 to 2.54).

Prior: Uniform (0, 5)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.912	–3.24 to –0.62[a]
Physical therapy without mobilisation	5	–1.71	–3.43 to 0.008
Steroid	3	–1.14	–2.43 to 0.16
Physiotherapy + placebo	4	–0.93	–2.22 to 0.34

a Did not cross line of no effect.
Data points: 7; residual deviance: 5.51; τ^2 (between-study variance): 0.70 (95% CrI 0.0002 to 5.87).

Prior: Uniform (0, 10)			
Comparator: placebo			
		SMD	
Treatment	**Node no.**	**Mean**	**95% CrI**
Steroid + physiotherapy	2	–1.91	–3.35 to –0.54[a]
Physical therapy without mobilisation	5	–1.71	–3.55 to 0.14
Steroid	3	–1.15	–2.51 to 0.25
Physiotherapy + placebo	4	–0.93	–2.32 to 0.43

a Did not cross line of no effect.
Data points:7; residual deviance: 5.5; τ^2 (between-study variance): 1.03(95% CrI 0.0002 to 7.64).

Appendix 11

Economic evaluation study quality checklist

Study assessed: van den Hout 2005[93]

	Item		
	Study design	**Response**	**N/A**
1	The research question is stated	Yes	
2	The economic importance of the research question is stated	Yes	
3	The viewpoint(s) of the analysis are clearly stated and justified	Yes	
4	The rationale for choosing the alternative programmes or interventions compared is stated	Yes	
5	The alternatives being compared are clearly described	Yes	
6	The form of economic evaluation used is stated	Yes	
7	The choice of form of economic evaluation is justified in relation to the questions addressed	Yes	
	Data collection		
8	The source(s) of effectiveness estimates used are stated	Yes	
9	Details of the design and results of effectiveness study are given (if based on a single study)	No	
10	Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)		N/A
11	The primary outcome measure(s) for the economic evaluation are clearly stated	Yes	
12	Methods to value health states and other benefits are stated	Yes	
13	Details of the subjects from whom valuations were obtained are given	Yes	
14	Productivity changes (if included) are reported separately	Yes	
15	The relevance of productivity changes to the study question is discussed	Unclear	
16	Quantities of resources are reported separately from their unit costs	Yes	
17	Methods for the estimation of quantities and unit costs are described	Yes	
18	Currency and price data are recorded	Yes	
19	Details of currency of price adjustments for inflation or currency conversion are given	Yes	
20	Details of any model used are given		N/A
21	The choice of model used and the key parameters on which it is based are justified		N/A
	Analysis and interpretation of results		
22	Time horizon of costs and benefits is stated	Yes	
23	The discount rate(s) is stated		N/A
24	The choice of rate(s) is justified		N/A
25	An explanation is given if costs or benefits are not discounted		N/A
26	Details of statistical tests and confidence intervals are given for stochastic data	Yes	
27	The approach to sensitivity analysis is given	No	
28	The choice of variables for sensitivity analysis is justified		N/A
29	The ranges over which the variables are varied are stated		N/A
30	Relevant alternatives are compared	Yes	
31	Incremental analysis is reported	Yes	
32	Major outcomes are presented in a disaggregated as well as aggregated form	Yes	
33	The answer to the study question is given	Yes	
34	Conclusions follow from the data reported	Yes	
35	Conclusions are accompanied by the appropriate caveats	Yes	

Response categories: Yes, No, Unclear. Authors may enter N/A if an item on the checklist is not appropriate, but this is only acceptable for items 9,10, 12-15, 20, 21, 23-29, and 31. Drummond checklist: Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. BMJ
Source: http://resources.bmj.com/bmj/authors/checklists-forms/health-economics

Appendix 12

Economic evaluation data extraction/summary

Study assessed: van den Hout 2005[93]

Type of economic evaluation: Cost–utility analysis.

Study objective: To compare high-grade and low-grade mobilisation techniques in patients with frozen shoulder (FS).

Interventions: The interventions compared were high-grade mobilisation comprising mobilisation techniques that are performed in the end ranges of the limited joint mobility of the shoulder. The duration of prolonged stress in the end-range position was varied according to individual patient tolerance. Low-grade mobilisation was performed under the explicit instruction that the technique should be performed without causing any pain to the patient. Patients were treated for 30 minutes twice weekly over a period of 12 weeks. From 6 weeks onwards treatments could be reduced in frequency, or stopped if the therapist felt that the shoulder had returned to a normal range of motion. The only concomitant treatment allowed was pain relief. The history of treatment was variable although a high percentage of patients in each group (64% HGMT and 58% LGMT) had received multiple steroid injections prior to enrolling in the trial.

Location/setting: The study was conducted in a tertiary care setting in the Netherlands.

Analytical approach: The economic evaluation was conducted concurrently with a RCT.[40] The trial enrolled 100 patients who had suffered from unilateral adhesive capsulitis for at least 3 months and who had experienced at least a 50% decrease in passive joint mobility. An ITT analysis was conducted. Missing data were imputed by carrying forward the last available measurement. Differences were tested using double-sided non-parametric bootstrapping. The time horizon appears to have been 12 months and the analysis was conducted from a societal perspective.

Effectiveness/utility data: No clinical efficacy data were presented in the paper. Data on utilities were estimated using the SF-6D utility index, which was calculated from SF-36 response data collected alongside the trial at baseline and at 3, 6 and 12 months' follow-up. Only SF-6D data were presented.

Resource use/cost data: Resource-use information was collected using quarterly cost questionnaires. Dutch standard prices, which were designed to reflect social costs and standardise economic evaluations, were used. Where standard prices were not available, charges were used. Costs included treatment sessions, alternative medicine sessions, hospitalisations (MUA, acromioplasty), home nursing care, medication, travel costs and non-health-care costs (labour and domestic help).

Results: The average annual health-care costs per patient were €2552 for HGMT and €2293 for LGMT, a difference of €259 in favour of LGMT ($p = 0.58$, 95% CI –€644 to €1162). The average annual societal costs per patient were €8809 for HGMT and €6911 for LGMT, a difference of €1898 in favour of LGMT ($p = 0.37$, 95% CI –€2551 to €5711).

The average QALYs were 0.695 for HGMT and 0.702 for LGMT, a difference of 0.007 ($p = 0.71$, 95% CI –0.32 to 0.049).

Although results did not reach statistical significance, both cost and utility results favoured LGMT over HGMT.

Appendix 13

Resource-use table

Resource use for the interventions identified from the primary studies included in the review

Intervention	Resource use		
	Health professionals involved (physiotherapist, GP, other)	Setting (community, hospital)	Quantities (no. of sessions, duration, etc.)
Steroid therapy alone	Guided injection (hospital doctor, either trainee or consultant, orthopaedic surgeon, rheumatologist, radiologist, anaesthetist)	Hospital	Three sessions: first session (initial assessment), 30 minutes; two follow-up sessions each 1 hour with injection
	Unguided injection delivered by physiotherapist or GP	Community	Physiotherapist: three sessions: first session (initial assessment) 20 minutes; two follow-up sessions with injection each 10–20 minutes
			GP: three sessions: first session (initial assessment) 10–12.5 minutes; two follow-up sessions each 10–12.5 minutes
Active PT	Physiotherapist	Community/hospital	Six sessions of 30 minutes' duration delivered in either setting
			Following guided injection, referral to physiotherapist for six sessions of 30 minutes' duration
			Following injection from physiotherapist, six sessions of 30 minutes' duration
			Following injection from GP, referral to physiotherapist for six sessions of 30 minutes' duration
			OR
			Active PT is delivered at the same time as injection in all settings = no extra sessions/time required
Sodium hyaluronate	Hospital consultant	Hospital	One injection, 30–60 minutes; one review visit
Electroacupuncture[a] + other PT	Physiotherapist	Either	Delivered in six sessions plus additional component of PT by a physiotherapist, adding maybe 15 minutes to a 20- to 30-minute session
'Normal' acupuncture + active PT	As above	Either	As above – delivered in six sessions plus additional component of PT by a physiotherapist, adding maybe 15 minutes to a 20- to 30-minute session
MUA	Orthopaedic surgeon and anaesthetist; operating theatre staff, usually one anaesthetic nurse and a surgical scrub nurse	Secondary care hospital	General anaesthesia and MUA likely to take on average 15 minutes. Recovery from anaesthesia variable, typically may take a further 15 minutes. Plus final/follow-up review with orthopaedic surgeon
			Base case 30 minutes, general surgical procedure
Arthrographic distension	Radiologist or orthopaedic surgeon	Secondary care hospital	The procedure was assumed to require around 15 minutes and be delivered as a single injection over one visit
Capsular release	Physiotherapist, anaesthetist, orthopaedic surgeon, anaesthetic nurse, scrub nurse and assistant, recovery nurse	Secondary care hospital	30–45 minutes for the anaesthesia and release procedure. Recovery from anaesthesia further 15 minutes

PT, physiotherapy.

a According to definitions found in the studies included in the review, which involved the application of electrical stimuli to needles embedded in the skin.

Appendix 14

Exploratory mapping analysis

Mapping from SF-36 PCS and MCS onto EQ-5D

Pattern of EQ-5D scores and SF-36 (PCS, MCS) scores within the SAPPHIRE data set (for complete measurements at 1 month)

EQ-5D grouping	*n*	EQ-5D (mean)	SF-36 PCS (mean)	SF-36 MCS (mean)
< 0	11	–0.07	28.11	27.46
0–0.249	23	0.11	33.47	40.18
0.25–0.499	4	0.29	39.86	52.83
0.5–0.699	60	0.62	36.96	43.82
0.7–0.799	35	0.76	43.78	53.18
0.8–0.899	20	0.81	50.08	51.43
0.9–1.0	0	NA	NA	NA
Full index	18	1	52.48	55.05
Overall	171	0.59	40.49	46.19

NA, not applicable.

Pattern of EQ-5D scores and SF-36 (PCS, MCS) scores within the SAPPHIRE data set (for complete measurements at 3 months)

EQ-5D grouping	*n*	EQ-5D (mean)	SF-36 PCS (mean)	SF-36 MCS (mean)
< 0	10	–0.07	35.96	45.70
0–0.249	18	0.11	39.18	47.35
0.25–0.499	1	0.26	36.64	41.14
0.5–0.699	44	0.63	39.68	42.01
0.7–0.799	21	0.75	44.07	50.23
0.8–0.899	28	0.82	42.91	53.2
0.9–1.0	0	NA	NA	NA
Full index	11	1.0	40.68	48.95
Overall	133	0.59	40.79	47.21

NA, not applicable.

Pattern of EQ-5D scores and SF-36 (PCS, MCS) scores within the SAPPHIRE data set (for complete measurements at 12 months)

EQ-5D grouping	*n*	EQ-5D (mean)	SF-36 PCS (mean)	SF-36 MCS (mean)
<0	11	–0.12	27.81	29.83
0–0.249	11	0.09	32.00	38.27
0.25–0.499	1	0.26	21.51	47.41
0.5–0.699	49	0.61	34.52	43.54
0.7–0.799	30	0.75	45.54	48.71
0.8–0.899	32	0.82	50.13	53.35
0.9–1.0	0	NA	NA	NA
Full index	29	1	54.87	55.79
Overall	163	0.66	42.53	47.34

NA, not applicable.

Pattern of EQ-5D scores and SF-36 PCS and MCS scores within the SAPPHIRE data set (for complete responses) at different time points

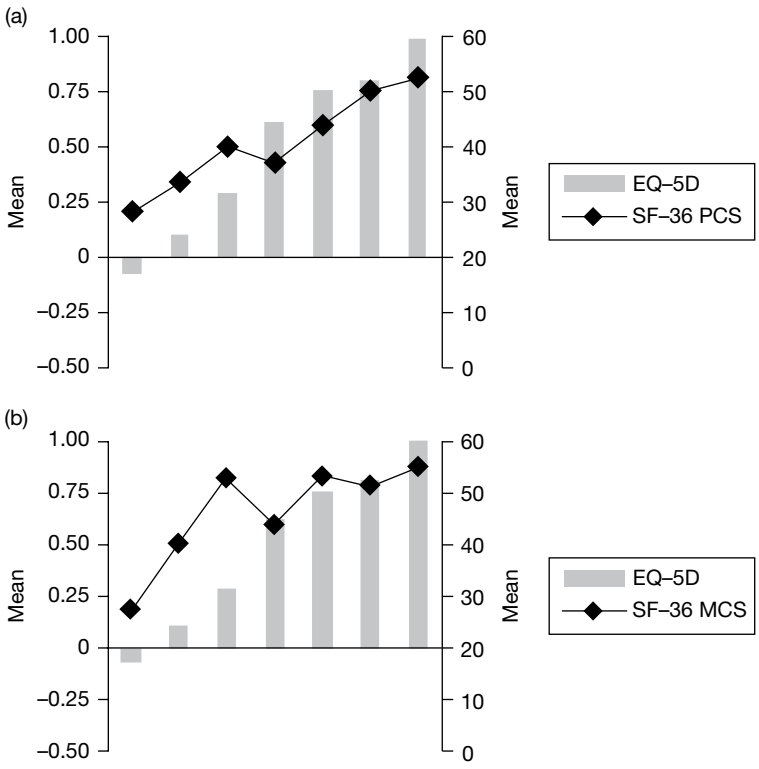

FIGURE 30 One-month follow-up. (a) EQ-5D and SF-36 PCS, (b) EQ-5D and SF-36 MCS.

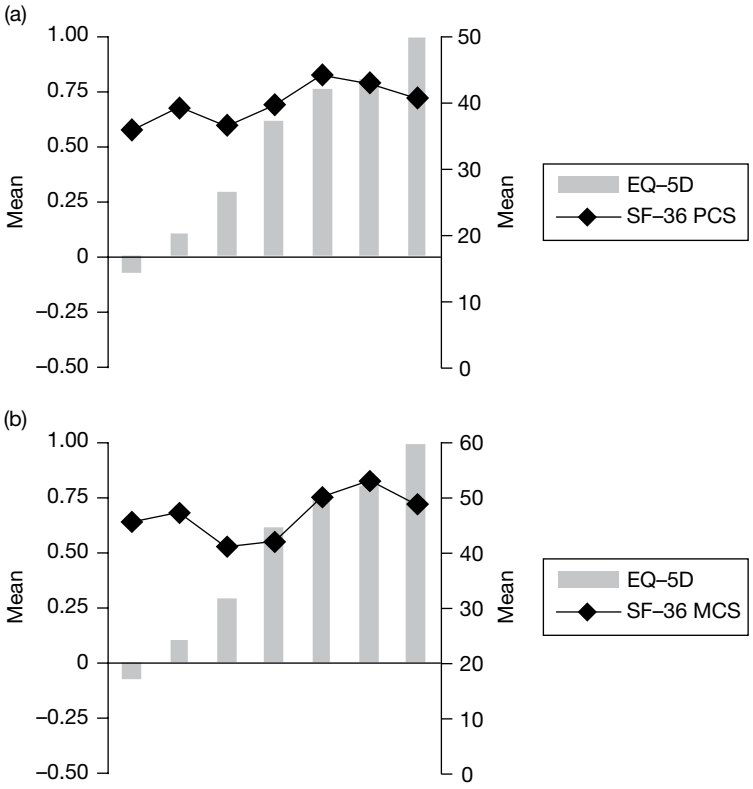

FIGURE 31 Three-month follow-up. (a) EQ-5D and SF-36 PCS, (b) EQ-5D and SF-36 MCS.

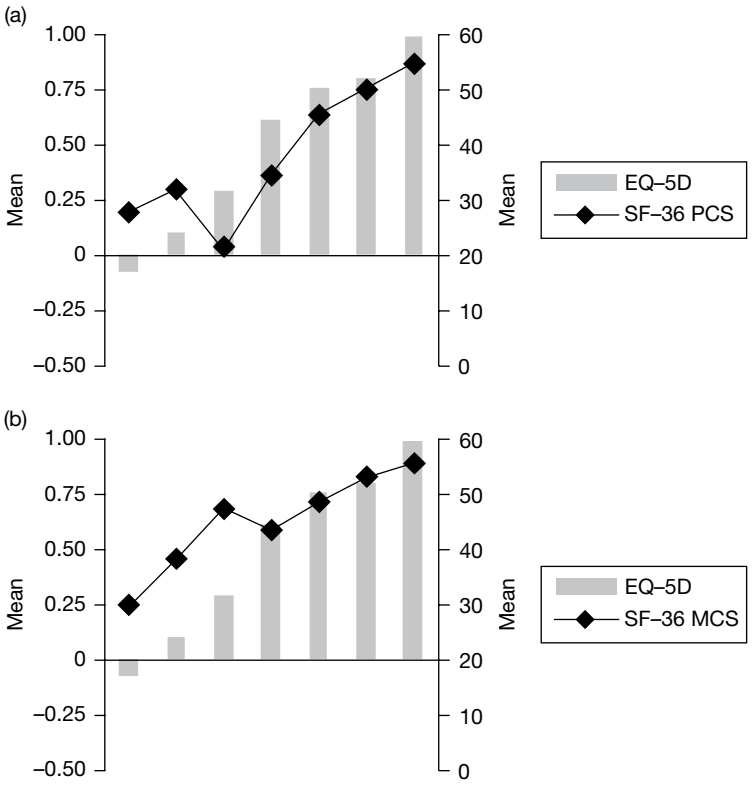

FIGURE 32 Twelve-month follow-up. (a) EQ-5D and SF-36 PCS, (b) EQ-5D and SF-36 MCS.

Regression models using main effects with and without squared terms and interaction term (using individual-level data at 1, 3 and 12 months)

	Model 1		**Model 2**		**Model 3**		**Model 4**		**Model 5**	
Econometric estimation method	OLS[a]		OLS[a]		OLS[a]		TOBIT		CLAD	
Independent variables	PCS MCS		PCS MCS, squared terms		PCS MCS, squared terms and interaction term		PCS MCS, squared terms and interaction term		PCS MCS, squared terms and interaction term	
	Coeff.	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***
Intercept	–0.2645051	0.004122	–0.947965	0.1748065	–1.378458	0.0449899	–1.171123	0.3070996	–1.839797	0.4490999
PCS	0.0139756	0.0015533	–0.0201276	0.0113677	0.0335792	0.0080814	0.023285	0.0108202	0.0568059	0.0155343
MCS	0.0065544	0.2287304	0.0366059	0.0081761	0.04406	0.0117933	0.0415846	0.0095459	0.0446596	0.0092294
PCS*PCS			–0.000091	0.000089	–0.0001066	0.0000965	–0.0000106	0.0001109	–0.000332	0.0001687
MCS*MCS			–0.003444	0.0001092	–0.000322	0.0001171	–0.0003238	0.0001014	–0.0002661	0.0000738
PCS*MCS					–0.0002528	0.0000856	–0.0001693	0.0001162	–0.0003647	0.0001247
Adjusted R^2	0.3840		0.4162		0.4284		–		–	
ME	–0.0025		–0.0039		–0.0020		–0.0235		–0.0265	
MAE	0.1889		0.1871		0.1861		0.1877		0.1815	
RMSE	0.254899		0.259112		0.25906		0.26508		0.266589	
|Difference|[b]										
$\|\Delta\| \leq 0.10$	154	82%	151	81%	154	82%	156	83%	154	82%
$\|\Delta\| \leq 0.05$	136	73%	130	70%	137	70%	139	74%	145	78%
$\|\Delta\| \leq 0.01$	85	45%	76	41%	88	47%	91	49%	102	55%
	Actual	***Predict***		***Predict***		***Predict***		***Predict***		***Predict***
Mean	0.6219	0.6244		0.6258		0.6239		0.6454		0.6484
SD	0.29191	0.19633		0.20683		0.20939		0.22937		0.21983
Min.	–0.18	0.20		–0.10		–0.09		–0.10		–0.07
Max.	1.00	0.92		0.90		0.92		1.01		0.86
Range[c]	1.18	0.72		1.01		1.01		1.11		0.93

SE, robust standard error.

a With adjustment for repeated measurements at 1, 3 and 12 months' follow-up.

b Proportion of predicted values with errors < |0.01|, |0.05| and |0.10|.

c Range = maximum value – minimum value

Total $n = 467$. Estimation data set = 280 (60%), validation data set = 187.

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Regression models using the main effects with and without squared terms and interaction term (using models estimated from 3-month data and used to predict EQ-5D scores at 12 months)

	Model 1		**Model 2**		**Model 3**		**Model 4**		**Model 5**	
Econometric estimation method	OLS[a]		OLS[a]		OLS[a]		TOBIT		CLAD	
Independent variables	PCS MCS		PCS MCS, squared terms		PCS MCS, squared terms and interaction term		PCS MCS, squared terms and interaction term		PCS MCS, squared terms and interaction term	
	Coeff.	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***
Intercept	0.2842682	0.1811317	–0.6233533	0.5770837	–1.552434	0.749881	–1.814838	0.7887539	–0.6770489	1.035821
PCS	0.004559	0.003425	0.0018081	0.0201721	0.0249701	0.0232969	0.0286508	0.0244527	0.0157259	0.0273862
MCS	0.0026323	0.0030736	0.0516204	0.0221907	0.073418	0.0246642	0.0831682	0.0259928	0.0399689	0.0316185
PCS*PCS			0.0000186	0.000258	0.0000464	0.0002541	0.000041	0.0002683	0.0000152	0.0002815
MCS*MCS			–0.0005561	0.0002495	–0.0005877	0.0002459	–0.0006711	0.0002584	–0.0002875	0.0002772
PCS*MCS					–0.00052	0.0002744	–0.0005816	0.0002883	–0.0002641	0.0003168
Adjusted R^2	0.0147		0.0513		0.0830		–		–	
ME	0.0662		0.0703		0.0761		0.0654		–0.0100	
MAE	0.1969		0.2045		0.2039		0.2672		0.1531	
RMSE	0.247936		0.266884		0.260014		0.351159		0.221678	
|Difference|[b]										
$\|\Delta\| \leq 0.10$	51	31%	55	34%	58	36%	58	36%	94	58%
$\|\Delta\| \leq 0.05$	23	14%	34	21%	39	24%	36	22%	56	34%
$\|\Delta\| \leq 0.01$	7	4%	15	9%	8	8%	17	6%	16	10%
	Actual	***Predict***		***Predict***		***Predict***		***Predict***		***Predict***
Mean	0.6690	0.6028		0.5987		0.5929		0.6037		0.6790
SD	0.29254	0.07250		0.1277		0.15807		0.19692		0.12368
Min.	–0.24	0.46		–0.20		–0.24		–0.50		0.10
Max.	1.00	0.71		0.76		0.86		0.91		0.84
Range[c]	1.02	0.256		0.607		0.755		0.846		0.541

SE, robust standard error.

a With adjustment for repeated measurements at 1, 3 and 12 months' follow-up.

b Proportion of predicted values with errors < |0.01|, |0.05| and |0.10|.

c Range = maximum value – minimum value

Validation data set = 163.

Actual versus predicted EQ-5D: mapping SF-36 PCS and MCS to EQ-5D

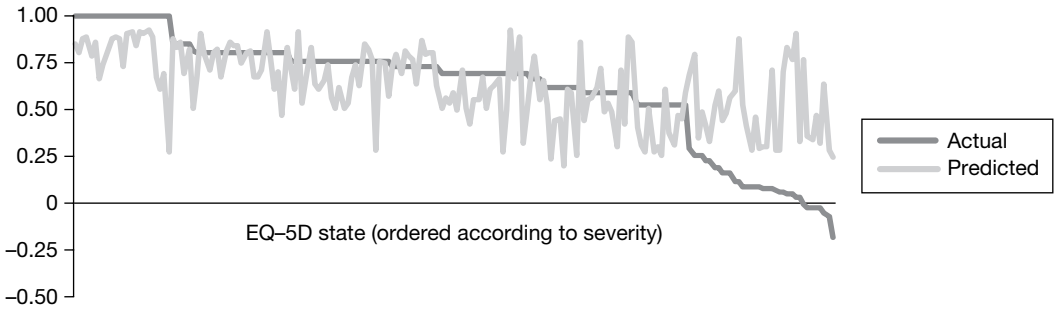

FIGURE 33 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, OLS1 model.

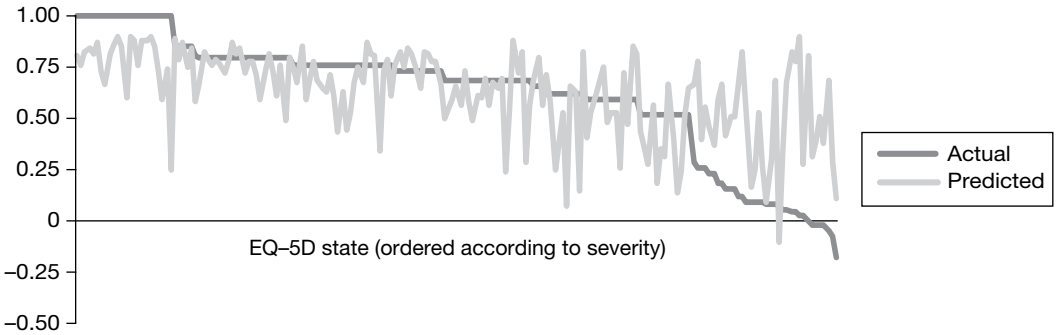

FIGURE 34 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, OLS2 model.

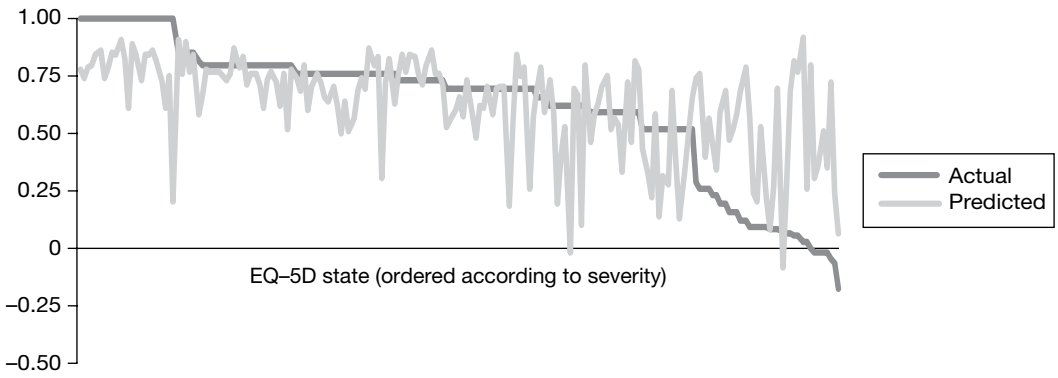

FIGURE 35 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, OLS3 model.

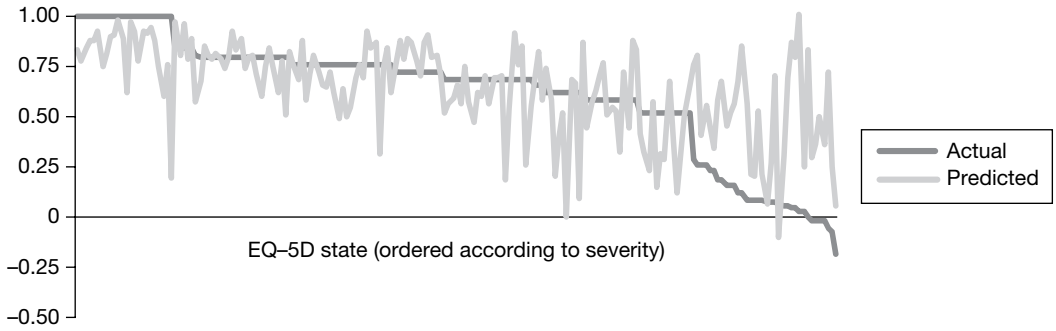

FIGURE 36 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, TOBIT model.

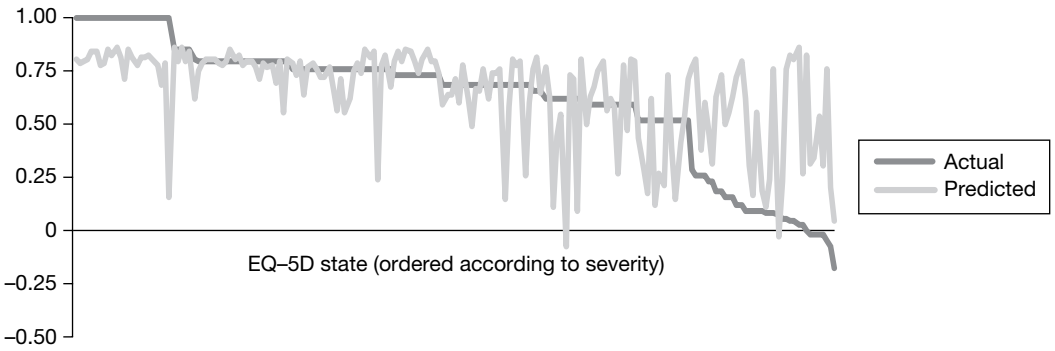

FIGURE 37 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, CLAD model.

Mapping from pain visual analogue scale onto EQ-5D

Pattern of EQ-5D scores and pain visual analogue scale scores within the SAPPHIRE data set (for complete measurements at 1 month)

EQ-5D grouping	*n*	EQ-5D (mean)	Pain VAS (mean)
< 0	11	–0.07	80.91
0–0.249	23	0.11	58.26
0.25–0.499	4	0.29	26.25
0.5–0.699	68	0.63	51.00
0.7–0.799	34	0.76	33.91
0.8–0.899	20	0.81	29.4
0.9–1.0	19	1.0	19.74
Full index	19	1.0	19.74
Overall	179	0.59	44.13

Pattern of EQ-5D scores and pain visual analogue scale scores within the SAPPHIRE data set (for complete measurements at 3 months)

EQ-5D grouping	*n*	EQ-5D (mean)	Pain VAS (mean)
< 0	8	–0.05	18.13
0–0.249	15	0.1	29.27
0.25–0.499	1	0.26	50
0.5–0.699	52	0.63	41.87
0.7–0.799	24	0.75	40.17
0.8–0.899	26	0.83	38.88
0.9–1.0	15	1.0	34.67
Full index	15	1.0	34.67
Overall	141	0.63	37.63

Pattern of EQ-5D scores and pain visual analogue scale scores within the SAPPHIRE data set (for complete measurements at 12 months)

EQ-5D grouping	*n*	EQ-5D (mean)	Pain VAS (mean)
< 0	12	–0.05	57.83
0–0.249	13	0.1	55.77
0.25–0.499	1	0.26	5
0.5–0.699	50	0.63	39.16
0.7–0.799	30	0.75	34.63
0.8–0.899	31	0.83	17.00
0.9–1.0	34	1.0	5.29
Full index	34	1.0	5.29
Overall	171	0.63	29.99

Pattern of EQ-5D scores and pain visual analogue scale scores within the SAPPHIRE data set (for complete responses) at different time points

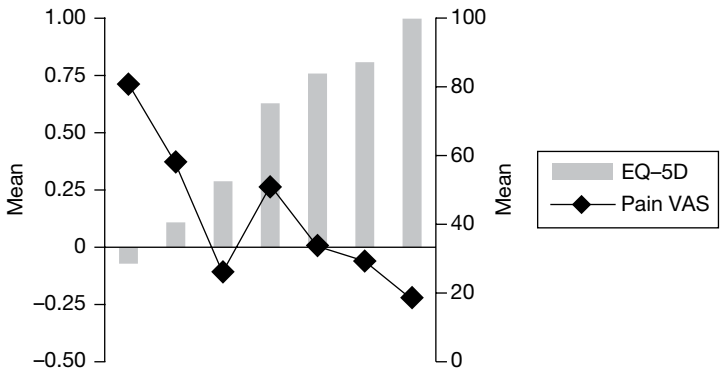

FIGURE 38 One-month follow-up.

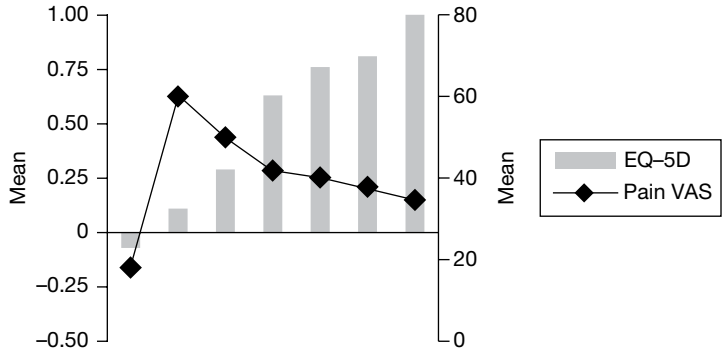

FIGURE 39 Three-month follow-up.

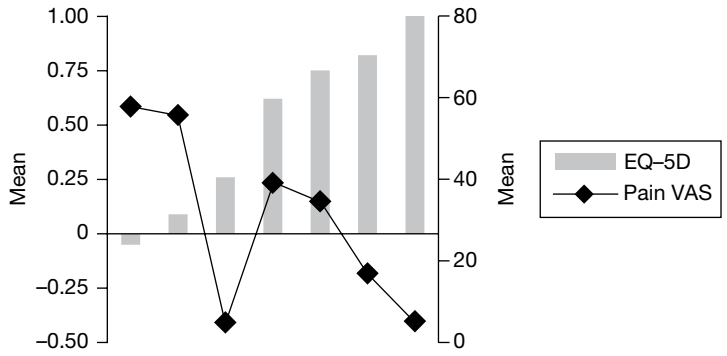

FIGURE 40 Twelve-month follow-up.

Regression models using pain visual analogue scale main effects with and without squared terms (using individual-level data at 1, 3 and 12 months)

	Model 1		**Model 2**		**Model 3**		**Model 4**	
Econometric estimation method	OLS		OLS		TOBIT		CLAD	
Independent variables	Pain VAS night		Pain VAS night, squared terms		Pain VAS night, squared terms		Pain VAS night, squared terms	
	Coeff.	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***
Intercept	0.7737689	0.0020501	0.735917	0.0860794	0.80135	0.80135	0.8	0.0242477
pVASnight	–0.0031619	0.0825151	–0.0033967	0.0024525	–0.0054838	–0.0054838	–0.0042917	0.0016361
pVASnight*pVASnight			0.0000028	0.0000104	0.0000199	0.0000199	0.0000208	0.00002
R^2	0.1009		0.1009		–		–	
ME	0.03051		0.03055		0.00183		–0.04091	
MAE	0.20144		0.20167		0.19449		0.18155vw	
RMSE	0.26497		0.26487		0.26403		0.26689	
IDifferenceI[a]								
I∆I≤ 0.10	69	35%	70	36%	73	37%	90	46%
I∆I≤ 0.05	39	20%	40	20%	39	20%	50	26%
I∆I≤ 0.01	5	3%	5	3%	8	4%	2	1%
	Actual	***Predict***		***Predict***		***Predict***		***Predict***
Mean	0.65250	0.62199		0.62195		0.65067		0.69341
SD	0.280635	0.096152		0.096383		0.118435		0.080537
Min.	–0.240	0.418		0.424		0.452		0.579
Max.	1.00	0.734		0.736		0.801		0.800
Range[b]	1.240	0.316		0.312		0.349		0.221

SE, robust standard error.

a Proportion of predicted values with errors < I0.01I, I0.05I and I0.10I.

b Range = maximum value – minimum value.

Total n = 491. Estimation data set = 295 (60%), validation data set = 196.

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Regression models using the main effects with and without squared terms and interaction term (using models estimated from 3-month data and used to predict EQ-5D scores at 12 months)

	Model 1		**Model 2**		**Model 3**		**Model 4**	
Econometric estimation method	OLS		OLS		TOBIT		CLAD	
Independent variables	Pain VAS night		Pain VAS night, squared terms		Pain VAS night, squared terms		Pain VAS night, squared terms	
	Coeff.	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***	***Coeff.***	***SE***
Intercept	0.5540896	0.0524505	0.5353785	0.0663995	0.5413921	0.0725511	0.6872609	0.0621687
pVASnight	0.0013853	0.0010672	0.0033283	0.0043293	0.0042145	0.0047531	0.0009522	0.0036473
pVASnight*pVASnight			–0.000023	0.0000497	–0.0000312	0.0000546	–0.000013	0.0000385
R^2	0.0081		–0.0014		–		–	
ME	0.03958		0.0402		0.0206		–0.0479	
MAE	0.21718		0.2218		0.2158		0.1877	
RMSE	0.276951		0.280038		0.280351		0.279724	
|Difference|[a]								
$\|\Delta\| \leq 0.10$	41	24%	40	23%	48	28%	67	39%
$\|\Delta\| \leq 0.05$	18	11%	21	12%	22	13%	36	21%
$\|\Delta\| \leq 0.01$	5	3%	2	1%	7	4%	20	12%
	Actual	***Predict***		***Predict***		***Predict***		***Predict***
Mean	0.66409	0.59563		0.59442		0.61247		0.69277
SD	0.304862	0.041060		0.048773		0.057819		0.009118
Min.	–0.240	0.554		0.535		0.541		0.659
Max.	1.000	0.687		0.656		0.684		0.705
Range[b]	1.240	0.133		0.120		0.142		0.046

SE, robust standard error.

a Proportion of predicted values with errors < |0.01|, |0.05| and |0.10|.

b Range = maximum value – minimum value.

Validation data set = 171.

Actual versus predicted EQ-5D: mapping pain visual analogue scale to EQ-5D

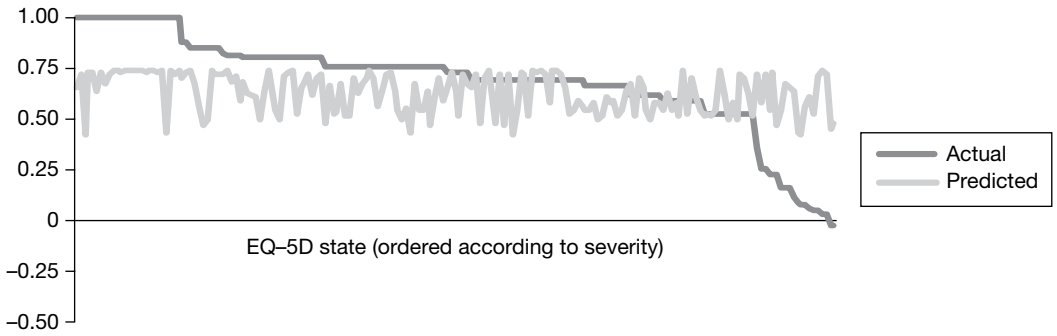

FIGURE 41 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, OLS1 model.

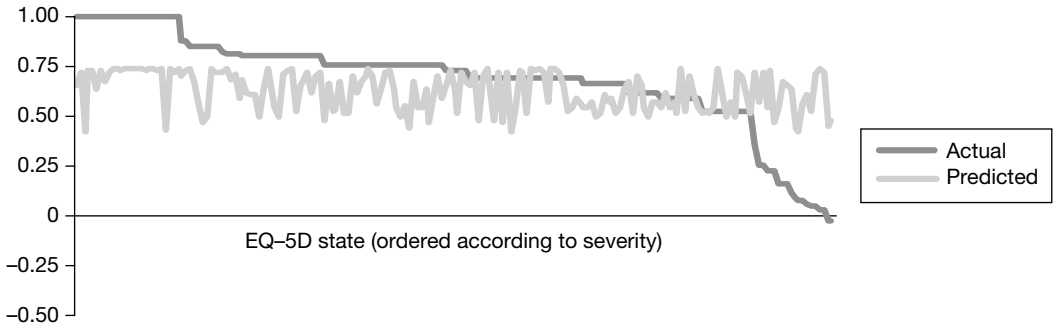

FIGURE 42 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, OLS2 model.

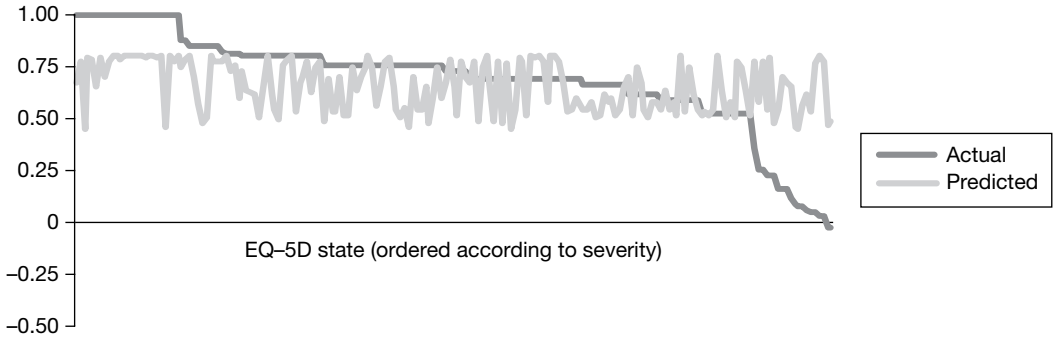

FIGURE 43 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, TOBIT model.

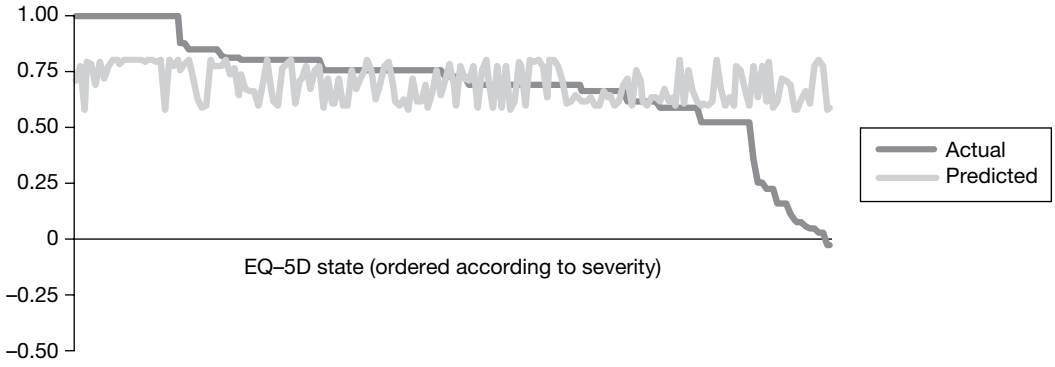

FIGURE 44 Observed and predicted EQ-5D scores using 1, 3 and 12 months' data, CLAD model.

Appendix 15

Protocol

Management of frozen shoulder: a systematic review and decision analytic model (HTA No. 09/13)

RESEARCH PROTOCOL 1.1

1. Research objectives

The overall aim of the research project is to determine the clinical and cost effectiveness of different methods of managing frozen shoulder, with the following specific objectives:

1. to evaluate, via a systematic review, the clinical effectiveness (including adverse effects) of strategies currently used in the NHS for the management of frozen shoulder and identify the most appropriate intervention by stage of condition; specifically physical therapies, steroid and other shoulder injections, manipulation under anaesthesia, arthrographic distension, capsular release, watchful waiting and combinations of these interventions;
2. to evaluate, via a systematic review, the cost-effectiveness of the different interventions in order to inform the development of a decision model;
3. to develop a decision analytic model to estimate the cost-effectiveness of alternative treatment options for frozen shoulder;
4. to make recommendations for clinical practice; and
5. to identify any gaps in the evidence, undertake value of information (VoI) analysis to assess the potential value of future research on interventions for frozen shoulder and to make specific recommendations for further research.

2. Background

Frozen shoulder, also known as adhesive capsulitis, is a very painful condition of unknown aetiology, in which movements of the shoulder become severely restricted. The condition is thought to be the result of inflammation and swelling in the lining of the shoulder joint (capsule) and its associated ligaments, with resultant contracture of the shoulder joint capsule. Bunker describes pathology of fibrous contracture of the rotator interval and coracohumeral ligament of the shoulder joint.[1] The lining loses its normal characteristic of flexibilty and elasticity and becomes stiff and painful. The three key characteristics of frozen shoulder are gradual onset of shoulder stiffness, severe pain, especially at night, and near complete loss of passive and active external rotation of the shoulder.[2] Typically there are three overlapping phases of frozen shoulder:[2]

- Phase 1 (painful freezing phase) – there is progressive stiffening and loss of motion in the shoulder with increasing pain on movement which may be worse at night (months 2 to 9);
- Phase 2 (adhesive phase) – there is a gradual decrease in pain but stiffness remains and there is considerable restriction in the range of movement (months 4 to 12);

- Phase 3 (resolution phase) – there is an improvement in range of movement (months 12 to 42).

Although the condition is classically described as having a resolution phase there may not be a complete resolution for all patients. There is variation across case series in the proportion of patients who do not regain full shoulder motion,[2] possibly a reflection of variation in how outcome was assessed. Based on the largest series of patients with a mean follow-up of 4.4 years from onset of symptoms, 59% had normal or near normal shoulders, 35% had mild to moderate symptoms with pain being the most common complaint, and 6% had severe symptoms.[3] Recurrence is unusual though it is estimated that the other shoulder becomes affected in 6–17% of patients within 5 years.[2]

The cumulative incidence of frozen shoulder is estimated at approximately 2.4/1000 per year based on a Dutch general practice sample.[4] It most commonly occurs in people in their mid-50's and is slightly more common in women than men. In addition to primary or idiopathic frozen shoulder, there is an association between frozen shoulder and a number of other medical conditions, in particular diabetes. The incidence is reported to be 10% to 36% amongst people with diabetes, who tend not to respond as well to treatment.[2]

Diagnosis and management

Diagnosis is based on clinical examination and medical history and a key alerting feature is restriction of shoulder movement in all directions.[5] Blood tests, X-rays and ultrasound are usually normal and not routinely required unless history or physical examination suggest the need to rule out other pathologies.[5]

Frozen shoulder is commonly managed in the primary care setting. There are a number of management options, both surgical and non-surgical, but there is no consensus about management. The aims of treatment, depending on stage of condition, are pain relief, increasing arm movement, reducing the duration of symptoms and return to normal activities for the patient. Treatment options include:

- Watchful waiting or 'supervised neglect', which involves explaining the condition to the patient and advising mobilisation within pain limits.
- Oral medications such as non-steroidal anti-inflammatory drugs (NSAIDs) and oral steroids. Although the use of oral steroids is described in the literature they are not a commonly used intervention in the UK.
- Gentle exercise supervised by a physiotherapist or as part of a home exercise program.
- Physical therapies to help regain range of movement and prevent further stiffness. Several different regimes have been described in the literature including supervised exercises, mobilisation, acupuncture, and use of electrotherapeutic interventions such as laser therapy and ultrasound.
- Intra-articular corticosteroid injections to reduce inflammation and provide pain relief. A range of different doses and number of injections are described in the literature. This intervention is usually delivered in the primary care setting but also in the secondary care setting, depending on how services are organized in a particular region.
- Arthrographic distension (also called hydrodilation) which involves controlled dilation of the joint capsule with sterile saline or other solution such as local anaesthetic or steroid guided by radiological imaging (arthrography). This is thought to break the adhesions, which frees up the joint, improving the range of movement. The procedure lasts approximately 15 minutes and is performed under local anaesthetic.

- Manipulation under anaesthesia (MUA) in which the shoulder is freed by rotation while the patient is under short general anaesthesia. This is usually a day procedure and generally lasts a maximum of 15 minutes including anaesthetic time.
- Arthroscopic capsular release, a surgical procedure conducted under general or regional anaesthesia during which the contracted tissue is released. It can be undertaken as keyhole surgery (arthroscopic) or open procedure. This can be undertaken as a day procedure.

These interventions can be used individually or in combination depending on the disease stage. The optimal timing of the interventions is unclear though there is a suggestion that aggressive mobilisation should be avoided in the early, severely painful phase.[5] Surgical intervention is generally, though not exclusively, used where the condition is resistant to the other interventions. There are variations across the country in the order in which treatments are provided, though usually a step-up approach is adopted in terms of degree of invasiveness of the treatment, from primary to secondary care settings. The most commonly used or recommended interventions by G.P.'s, physiotherapists and orthopaedic surgeons in the NHS, based on a recent survey, were conservative treatment (watchful waiting, education, oral pain relief), physical therapy (mainly physiotherapy and mobisilation) and intra-articular injection during the early 'painful' phase and conservative treatment, physical therapy, intra-articular injection and surgery (mainly manipulation under anaesthesia and arthroscopic capsular release) for patients in the 'resolution' phase.[6]

Existing research

We conducted scoping searches of the literature to inform the research proposal which involved searching key sources for clinical guidelines, systematic reviews and cost-effectiveness analyses (Appendix A). We identified only one guideline, from the New Zealand Guidelines Group, which was published five years ago and is therefore due for updating.[5] Clinical Evidence, last updated in February 2006, reviewed the evidence on interventions for shoulder pain in general.[7] Although several treatments were classified as likely to be beneficial, these were mainly in relation to other shoulder disorders. MUA plus intra-articular injection was identified as of likely benefit in people with frozen shoulder.

Systematic reviews were identified evaluating oral steroids,[8] corticosteroid injections,[9] physiotherapy,[10,11] acupuncture[12] and arthrographic distension,[13] but not manipulation under anaesthesia or arthroscopic release (*Table 1*). Some of these reviews focused on shoulder pain in general, and included a range of conditions. None of the literature searches for the reviews identified are recent. The preliminary scoping searches also indicate that there may be limited evidence on the cost-effectiveness of these treatments for frozen shoulder. Two of the studies we identified were in relation to treatment of people with chronic shoulder complaints[14] and new episodes of unilateral shoulder pain in primary care.[15] One study investigated the effectiveness and cost-effectiveness of physiotherapy following glenohumeral joint distension specifically in relation to patients with frozen shoulder.[16]

It is apparent from previous reviews that there is variation in how frozen shoulder is defined across studies. A review of 21 randomised controlled trials (RCTs) of interventions for frozen shoulder could not derive a consistent description of the condition from the trials investigating this patient group.[17] The included RCTs required that participants had restricted shoulder movement but there was inconsistency across trials in the number of degrees of restriction, the type of restriction (active or passive) and the direction of the restriction (abduction or external rotation).[17] This highlights the difficulty of applying a strict definition for frozen shoulder within the context of a systematic review.

TABLE 1 Potentially relevant reviews identified during rapid appraisal of the evidence

Author	Intervention	End date for literature search
Buchbinder *et al.*[8]	Oral steroids	November 2005
Buchbinder *et al.*[13]	Arthrographic distension	November 2006
Buchbinder *et al.*[9]	Corticosteroids (for shoulder pain)	June 2002
Cleland & Durall[11]	Physical therapy	December 2000
Green *et al.*[10]	Physiotherapy (for shoulder pain)	June 2002
Green *et al.*[12]	Acupuncture (for shoulder pain)	December 2003
Shah & Lewis[18]	Corticosteroid injections	June 2006

3. Research methods

We will undertake a systematic review of the literature on the effectiveness of different methods of managing frozen shoulder, with particular reference to the stage of the condition. The systematic review will inform the development of a decision analytic model. This will be a large and complex project which will involve undertaking a systematic review of six different interventions, one of which (physical therapy) encompasses several different types of therapy, as well as a decision model that reflects the complexity of management of the condition.

3.1 Systematic review of effectiveness of interventions

Search strategy

Both published and unpublished literature will be identified from systematic searches of electronic sources, hand searching, consultation with experts in the field, and reference checking.

The following databases will be searched: MEDLINE, MEDLINE In-Process, Cumulative Index to Nursing & Allied Health (CINAHL), EMBASE, Science Citation Index, BIOSIS Previews, PEDro, Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA) database, Cochrane Central Register of Controlled Trials (CENTRAL), PASCAL, Manual, Alternative and Natural Therapy (MANTIS) and Latin American and Caribbean Health Sciences (LILACS). Searches of electronic databases will not be restricted by language or study type.

In addition, information on studies in progress, unpublished research or research reported in the grey literature will be sought by searching a range of relevant databases including Conference Proceedings Citation Index, Science, Health Management Information Consortium (HMIC), ClinicalTrials.gov and NTIS.

Selected musculoskeletal disease websites will also be searched such as those of the National Institute of Arthritis & Musculoskeletal and Skin Diseases (NIAMS), the British Elbow & Shoulder Society (BESS), National Physiotherapy Research Network and Primary Care Rheumatology Society.

The MEDLINE search strategy is provided in Appendix B. This will be converted to run appropriately on other databases.

[Protocol addition: Where papers are not available from the British Library, extended searches will be undertaken only for papers published after 1965 and where it was in a language where we have identified a translator.]

Inclusion criteria

Systematic reviews and primary studies will be included if they meet the following criteria:

Population: patients with idiopathic (primary) frozen shoulder (adhesive capsulitis) will be included [Protocol addition: studies where at least 90% of the participants had primary frozen shoulder will be included]. Ideally, only patients with loss of active and passive external rotation of the involved shoulder with a normal x-ray would be included. This would allow for exclusion of patients with arthritis of the shoulder which can present as a similar clinical picture. However, based on a sample of the studies we have examined for the application, x-rays are not generally used to exclude joint arthritis. We will therefore take a pragmatic approach and include studies based on the authors' definition of frozen shoulder to ensure we have identified all the relevant evidence. (The impact of how frozen shoulder is defined will then be explored in the synthesis). Studies of general shoulder conditions will only be included if outcome data are reported separately for participants with frozen shoulder. Frozen shoulder in people with diabetes is defined as primary in some classifications and in others as secondary frozen shoulder. In this review this group is defined as having primary frozen shoulder and will therefore be included in the review.

Intervention: The following interventions, either alone or in combination, will be included:

- physical therapies including physiotherapy, acupuncture, chiropractic and osteopathy interventions). Physiotherapy encompasses a wide range of techniques including mobilisation, biofeedback, ultrasound and laser therapy and all therapies falling under the physiotherapy umbrella will be eligible for inclusion
- arthrographic distension
- steroid and other shoulder injections such as sodium hyaluronate
- manipulation under anesthesia
- capsular release (arthroscopic and open) and combinations of these treatments will be included
- the approach of 'watchful waiting' will also be included.

There are a number of other treatments that have been researched that are not commonly used on the NHS such as radiotherapy, collagenase injection, salmon calcitonin and antibodies to tumour necrosis factor-α. These interventions will not be included in the synthesis, though information will be collated on the number of studies assessing uncommon treatments and their study design.

[Protocol addition: Studies of acupuncture will be included only where the comparator is one of the other treatments of interest in the review. This excludes studies comparing different forms of acupuncture and studies comparing acupuncture with alternative therapies such as moxibustion.]

Comparator: Any of the above treatments studies (including studies comparing different regimens of the same intervention), no treatment or placebo.

Outcomes: pain (at rest, on movement, at night); range of movement (e.g. internal and external rotation, elevation); function and disability; quality of life; time to recovery, return to work and recreation; and adverse events.

Study design: Only randomised controlled trials (RCTs) will be eligible for inclusion where this level of evidence is available on an intervention/management strategy. In the absence of randomised trials, quasi-experimental studies (i.e. with a control group) will be eligible for inclusion. If controlled trials are not available for MUA or capsular release, which is likely to be the case, case series will be included. Only case series of at least 50 participants will be included

due to the problems of small case series being unrepresentative the clinical population. Where important adverse effects data may not be captured in RCTs, other study designs will also be considered to inform the economic model.

Systematic reviews will be included if (1) they fulfill all the relevant criteria, (2) have no significant sources of error and bias and (3) are reported in detail and the raw data are available from the report or authors to allow an update of the synthesis (if searches are more than 12 months out of date). If they do not meet all the criteria, systematic reviews will be used as sources of potentially relevant studies. It is anticipated that most of the systematic reviews available will be sources of relevant primary studies.

Screening and study selection

Two researchers will independently screen all titles and abstracts obtained through the searches for potentially relevant studies. Full manuscripts of potentially relevant studies will be ordered and two researchers will independently assess the relevance of each study using the criteria above. Discrepancies will be resolved by consensus or recourse to a third researcher if necessary.

Data extraction

A data extraction form will be developed, piloted on a small selection of studies and adjusted as necessary. Data extracted will include details of the study methods, setting, patient characteristics (including stage of condition), intervention, comparators, outcome measures and results. Data will be extracted into EPPI-Reviewer (a software package for managing systematic review production).

For continuous outcomes the post-intervention mean (and standard deviation) for each group will be extracted, where available. Otherwise the mean change from baseline for each group will be extracted.

Authors will be contacted where clarification of data is required for any of the primary outcomes (see synthesis below). Standard data imputation methods will be used, where necessary.[19]

Data extraction will be undertaken by one researcher and checked by another, with discrepancies resolved by consensus or recourse to a third researcher if necessary.

Quality assessment

Quality assessment will also be undertaken by one researcher and checked by a second with discrepancies resolved by consensus or recourse to a third researcher if necessary. Studies will be quality assessed using the checklist in Appendix C. The criteria for assessing randomized and nonrandomised trials are based on recent CRD guidance;[20] the criteria for case series are based on those used in recent systematic review including case series.[21]

Data synthesis

The synthesis will focus on comparing the main treatment options (for example whether mobilization is more effective with or without steroid injection during the adhesive phase of the disease), rather than the effect of small variations in approach within the treatment classes. However, in reality there may be considerable variability within the different treatment options which will influence the type of analyses that are possible.

The primary outcomes will be patient-assessed pain intensity, quality of life (including disability measures such as the Oxford Shoulder Score and generic quality of life such as SF-36) and range of movement. Given that the symptoms of frozen shoulder change over time (with pain being

the strongest characteristic of the early stages but not later) it is not appropriate to use a single primary outcome. Other outcomes such as time to return to work will be considered, evidence permitting. In addition to the proposed primary outcomes being the most clinically useful and patient-focused, it will also be more feasible to map these onto a utility measure for the decision model than the secondary physiological outcomes. Adverse effects of treatment will also be considered.

A narrative and tabular summary of key study characteristics, results and quality assessment will be provided. Where appropriate (based on clinical and statistical heterogeneity and the necessary data being available) individual study results will be combined in a series of pair-wise meta-analyses based on type of intervention and comparator, using a random effects model. As it is anticipated that the measures used to assess continuous outcome (for example pain) will vary between studies, standardized mean differences will be calculated, where appropriate, and combined using the generic inverse variance method. Heterogeneity will be assessed using χ^2 tests[20] and inconsistency will be quantified using the I^2 statistic.[22]

Given the range of interventions being considered, a mixed treatment comparison or network analysis could permit ranking of the benefits and harms of the different treatments options.[23] However, the appropriateness of such an approach depends on the principle of exchangeability, i.e. that there are no systematic differences between the trials that test particular types of intervention. From the information we have gathered so far, and our clinical experience of the condition, we anticipate that the exchangeability assumption is unlikely to be met by the studies available. The treatment that patients currently receive is at least partly determined by the severity of symptoms, stage of the condition and progress with a given treatment modality. If this is reflected in the trials then it is unlikely, for example, that the populations included in trials of arthroscopic capsular release are similar to those where the intervention being investigated is home exercise. However, the feasibility and appropriateness of a MTC will be explored and conducted if appropriate.[24] Current guidance on good practice will be followed.[25]

Sub-group analyses will be restricted to a small number of potentially important characteristics that may reasonably be expected to modify the effect of the intervention. This will include sub-grouping studies based on how frozen shoulder was defined, stage of condition and/or severity (if such information is available), and whether study participants had diabetes.

Where meta-analysis is not appropriate a narrative synthesis will be undertaken. Where possible, results will be shown graphically. Studies will be grouped by type of intervention and comparator in the first instance and also the sub-groups identified above. Results will be interpreted in the context of the quality of the individual studies.

3.2 Systematic review of previous economic evaluations

A systematic review of economic evaluations will be undertaken to identify any models used previously and to inform the estimation of parameters for the decision model. Searches for economic evaluations of management strategies for frozen shoulder will be undertaken in the databases listed above (3.1). The search strategy will be adapted to focus on economic evaluations using search terms derived from the strategies used to identify studies for inclusion on the NHS Economic Evaluation Database (NHS EED) (see link for details http://www.crd.york.ac.uk/crdweb/html/helpdoc.htm#item17). In addition, searches of NHS EED and the Health Economic Evaluation Database (HEED) will be undertaken.

All full economic evaluations which meet the population and intervention inclusion criteria above will be eligible for inclusion.

A full economic evaluation will be defined as any study in which a comparison of two or more relevant alternatives was undertaken and with costs and outcomes examined separately for each alternative. This will include cost-effectiveness analysis (including cost–consequence analysis) where health outcomes are expressed in natural units; cost–utility analysis where benefits are measured in utility units or utility weighted life-years; and cost–benefit analyses, where benefits are measured in monetary form using approaches such as 'willingness to pay' or 'human capital approach'. Based on our preliminary scoping of the evidence available, we believe that only a small number of economic evaluations of management strategies for frozen shoulder are likely to be available. The quality of economic evaluations will be assessed based on a modified version of the Drummond checklist[26] and relevant data will be extracted.

3.3 Systematic review of service-users' views of interventions for frozen shoulder

Time permitting, a systematic review of the research literature on patients' views about interventions for frozen shoulder will also be undertaken.

Searches of MEDLINE, CINAHL and PsycINFO (from 1980 onwards) will be carried out. The search strategy used will be based upon the one used to identify studies for the effectiveness review (Appendix B) but will be adapted to include a qualitative design filter.[27]

Studies investigating patients views about the treatments included in the main review will be eligible for inclusion. Only English language qualitative studies assessing patients' views and experiences in relation to treatments for frozen shoulder will be eligible; expert opinion, letters containing no data on patient views, editorials and discussion papers will be excluded.

The processes for study selection, data extraction and quality assessment will follow those of the main review. Information extracted will include study aim, participant characteristics, methods of collecting data on patient views and experiences, method of analysis, results in the form of a summary of key themes arising from the analysis and authors' conclusions. Study quality will be assessed using a tool developed by Hawker *et al.*[28] A narrative synthesis of the data will be undertaken.

3.4 Development of a decision model

A decision analytic model will be developed to estimate the cost-effectiveness of the different treatments for frozen shoulder. The specific objectives of the cost-effectiveness analysis will be to (1) assess the cost-effectiveness of the named interventions for frozen shoulder to inform clinical practice and (2) to identify the key uncertainties relating to the cost-effectiveness analysis and to use these to inform future research priorities.

In developing the model, NICE guidance on methods for technology appraisal will be followed.[25] The approach will be as follows:

- A clinically relevant and appropriate decision model will be structured to map patients' care pathways for the alternative therapies, in a way that is clinically appropriate and accounts for the phase of condition when treatment is received. The effect of treatment on short and longer-term costs and health related quality of life will be considered. The clinical experts on the team (from general practice, physiotherapy and orthopaedic surgery) will review the structure of the model to ensure it has good clinical face validity and only those pathways considered clinically meaningful will be modelled. In addition, the results of a current survey of a large sample of healthcare professionals will be used to inform the model.

- Treatment order will be an important aspect to incorporate into the model. In the clinical setting there are variations in practice but, in general, a step up approach tends to be used in terms of treatment invasiveness, from primary to secondary care settings. The methods used to identify the optimum ordering of treatments will build on previous work undertaken by the CRD/CHE technology assessment group.[29]
- An appropriate time horizon will be chosen for the decision model that is long enough to capture the relevant costs and benefits. It is anticipated this will be at least 5 years duration.
- The model will be populated using the most appropriate data identified systematically from the literature and routine sources. The parameter point estimates and distributions for the effectiveness of the different interventions will be taken directly from the results of the systematic review. For those parameters where estimates are not available directly from the systematic review, the health economists, information specialist and the researchers undertaking the systematic review will work closely to identify the best quality evidence available for that parameter. The information specialist will work in close liaison with the health economist to identify the model questions. Information to answer these questions will be provided by focused searching of appropriate databases, statistical sources and other relevant sources of information. The quality of all data used in the model will be explicitly discussed. The specific details of the data to be used to populate the model will await the development of the model structure and systematic review.
- Health benefits will be expressed in terms of quality adjusted life years (QALYs).
- The primary analysis will calculate the incremental cost-effectiveness of the different strategies based on an assessment of long-term NHS and Personal Social Service costs and quality adjusted utility.
- The uncertainty in the data used to populate the model will be captured through the use of probabilistic modelling which requires that each input in the model is entered as a distribution rather than a fixed parameter. Using Monte Carlo simulation, this parameter uncertainty will be translated into uncertainty in the overall results. The results of this analysis will be presented graphically using cost-effectiveness acceptability curves which show the probability that each intervention is cost-effective conditional on a range of possible threshold values attached to an additional QALY.
- To inform future research priorities, the model will be used to undertake a value of information (VoI) analysis. Decisions based on existing information will inherently be uncertain. We propose to conduct an expected value of information analysis to help estimate the cost of this uncertainty and identify whether it is of value to conduct further research in this area. If the expected value of perfect information for the population of interest exceeds the expect costs of such additional research, then potentially, it will be cost-effective for further research to be funded to better inform this decision in the future.

3.5 Dissemination

It will be important to ensure that those who need to know about the results of this review are informed and make sense of the findings. A detailed dissemination strategy will be produced to ensure that key groups are informed about the findings. Health professionals often differ in the amount of information they want to receive. CRD's research into, and experience of disseminating the results of systematic reviews has repeatedly shown that providing a brief overview of the topic, results and implications is the best way to communicate important messages to time-poor health professionals. We will produce a short non-technical summary giving brief background details, information about the quality of evidence, the results and clinical implications. The summary report will be targeted to appropriate clinical groups throughout the UK, such as orthopedic surgeons, GPs and physiotherapists and via networks such as the National Physiotherapy Research Network, the British Elbow and Shoulder Society and the Primary Care Rheumatology Society. Publication of the findings will be press released and the potential for short articles in the relevant lay media explored.

Other dissemination activities will include the submission of papers for peer-reviewed publication and submission of abstracts to conferences. The results will also be made available on the CRD website. All dissemination activities will involve signposting those interested in further details to the full HTA report.

4. Advisory Group

The project Advisory Group will meet on three occasions and between meetings contact will be made with the group or individuals depending on the query. Three individuals who currently or previously have had frozen shoulder have also been invited to provide input in relation to: identifying the outcomes that have most significance for people with the condition and whether the care pathways underpinning the economic model reflect their experience. They will also be invited to comment on the non-technical summary of the final report.

5. Project timetable and milestones

The project will take place over a 12 month period (1 March 2010 to 14 March 2011). The key milestones are as follows:

■ Protocol development and peer review	Month 1–2	April 2010
■ Literature searches (including economics)	Month 3–4	April 2010
■ Screening and study selection	Month 4–5	May-June 2010
■ Develop decision model structure	Month 3–4	May-June 2010
■ Data extraction and checking	Month 5–6	June-July 2010
■ Populate decision model with parameters not derived from systematic review	Month 5–6	July-August 2010
■ Systematic review data analysis and synthesis	Month 7–9	August-October 2010
■ De-bug decision model, analysis including sensitivity analysis	Month 7–9	September to Nov 2010
■ Draft final report	Month 9–10	Nov-December 2010
■ Draft report to advisory panel	Month 11	January 2011
■ Address peer comments	Middle of month 12	February 2011
■ Submit final report	End of Month 12	14 March 2011
■ Draft summary and papers for dissemination		

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Appendix A Rapid appraisal search to identify systematic reviews, published and in progress, guidelines and ongoing primary research

Completed and ongoing reviews	
Cochrane Database of Systematic Reviews http://www.thecochranelibrary.com	17 (11)
DARE http://www.thecochranelibrary.com	18 (14)
HTA Database http://www.thecochranelibrary.com	6 (5)
SIGN Guidelines http://www.sign.ac.uk	0
NICE (published appraisals) http://www.nice.org.uk/guidance/TA/published	0
National Guideline Clearinghouse http://www.guidelines.gov	6 (3)
HSTAT http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat	0
National Coordinating Centre for Health Technology Assessment http://www.hta.nhsweb.nhs.uk/	0
TRIP http://www.tripdatabase.com	423 (4)
Economic evaluations	
NHS EED http://www.thecochranelibrary.com	8 (7)
Indexes to and summaries of clinical effectiveness sources including reviews, appraisals of reviews, and evidence based guidelines	
Clinical Evidence http://clinicalevidence.bmj.com/ceweb/index.jsp	1 (1)
Health Evidence Bulletins Wales http://hebw.uwcm.ac.uk/	0
Supplementary MEDLINE search	
MEDLINE http://ovidsp.ovid.com/	2969

Appendix B Search strategy

Database: Ovid MEDLINE(R)

Search Strategy:

(frozen adj6 shoulder$).ti.
(stiff$ adj3 shoulder$).ti.
(adhesive adj (capsulitis or capsulitides)).ti.
((bursitis or bursitides) adj6 shoulder$).ti.
((capsulitis or capsulitides) adj6 shoulder$).ti.
1 or 2 or 3 or 4 or 5
(frozen adj6 shoulder$).ab.
(stiff$ adj3 shoulder$).ab.
exp bursitis/
(adhesive adj (capsulitis or capsulitides)).ab.
((bursitis or bursitides) adj6 shoulder$).ab.
((capsulitis or capsulitides) adj6 shoulder$).ab.
((periarthritis or peri-arthritis or periarthritides or peri-arthritides or peri-capsulitis or pericapsulitis) adj6 shoulder$).ti,ab.
shoulder pain/
(shoulder$ adj3 (pain or pains or painful or complain$)).ti,ab.
Shoulder Impingement Syndrome/
(shoulder$ adj6 impinge$).ti,ab.
subacromial impingement syndrome.ti,ab.
7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
Arthrography/
(arthrograph$ adj6 (distension$ or distention$)).ti,ab.
(arthrogram$ adj6 (distension$ or distention$)).ti,ab.
(glenohumeral adj6 (distension$ or distention$)).ti,ab.
Dilatation/
(dilatation or hydrodilat$).ti,ab.
or/20-25
19 and 26
Arthroscopy/
(arthroscop$ adj6 (releas$ or decompress$ or capsulotom$)).ti,ab.
((capsular adj2 releas$) or interventional microadhesiolysis or capsulotomy).ti,ab.
or/28-30
19 and 31
Injections, Intra-Articular/
33 and 19
injections/
35 and 19
((bursa$ or intrabursa$ or intra bursa$ or periartic$ or peri artic$ or intraartic$ or intra artic$) adj3 inject$).ti,ab.
37 and 19
((subacromial or acromioclavicular or glenohumeral) adj3 inject$).ti,ab.
((extra articular or extraarticular or shoulder$) adj3 inject$).ti,ab.
34 or 36 or 38 or 39 or 40
exp Physical Therapy Modalities/
(physiotherapy or physiotherapies or physical therap$ or manual therap$).ti,ab.

(passive adj (motion or movement)).ti,ab.
CPM.ti,ab.
muscle stretching exercises/
(stretching or stretches).ti,ab.
(mobilisation or mobilization).ti,ab.
(exercise$ adj2 (program$ or strength$ or intervention$ or training or prescription$ or prescrib$)).ti,ab.
(exercise$ adj2 (therap$ or therapeutic)).ti,ab.
((home or supervis$) adj2 exercis$).ti,ab.
((pendular or pendulum) adj exercis$).ti,ab.
((isokinetic or resist$) adj2 exercise$).ti,ab.
or/42-53
19 and 54
exp Musculoskeletal Manipulations/
chiropractic$.ti,ab.
osteopath$.ti,ab.
(manipulat$ adj3 (anesthesia or anaesthesia or anesthetic$ or anaesthetic$)).ti,ab.
MUA.ti,ab.
56 or 57 or 58 or 59 or 60
19 and 61
(TENS or ALTENS).ti,ab.
((electric$ adj2 stimulat$) or (transcutaneous adj2 stimulat$) or (transdermal adj2 electrostimulat$) or (cutaneous adj2 electrostimulat$) or electroanalgesia or electro analgesia).ti,ab.
(muscle adj2 stimulat$).ti,ab.
(neuromodulation or neuro modulation or neurostimulation or neuro stimulation).ti,ab.
interferential.ti,ab.
or/63-67
19 and 68
biofeedback.ti,ab.
Biofeedback, Psychology/
or/70-71
19 and 72
cryotherapy/
ice/
diathermy/
hyperthermia, induced/
hot temperature/
((cold or ice or heat or hot) adj (pack$ or therap$ or treat$)).ti,ab.
(thermograph$ or thermotherap$ or thermo therap$ or hypertherm$ or hyper therm$ or diatherm$ or cryotherap$ or cryo therap$).ti,ab.
or/74-80
19 and 81
exp Laser Therapy/
ultrasonic therapy/
ultrasound.ti,ab.
Ultrasonography, Interventional/
(electrotherapeutic adj (intervention$ or treat$)).ti,ab.
or/83-87
19 and 88
magnetic field therapy/
pulsed electromagnetic field therapy.ti,ab.

((electromagnetic$ or magnetic$) adj3 field$).ti,ab.
(biomagnetic$ or bio magnetic$ or pulsed signal).ti,ab.
PEMF.ti,ab.
or/90-94
19 and 95
nerve block/
neuromuscular blockade/
(nerve adj2 block$).ti,ab.
or/97-99
19 and 100
exp Acupuncture Therapy/
acupuncture$.ti,ab.
(electroacupuncture$ or electro acupuncture$).ti,ab.
(osteopuncture$ or osteo puncture$).ti,ab.
(perioste$ adj3 (stimulat$ or therap$ or needling)).ti,ab.
or/102-106
19 and 107
massage/
(massag$ or acupressure or shiatsu or shiatzu or zhi ya or chih ya).ti,ab.
109 or 110
19 and 111
(rehabilitat$ adj2 (program$ or protocol$)).ti,ab.
19 and 113
((watch$ adj2 wait$) or (conservative adj2 treat$)).ti,ab.
19 and 115
(management adj2 (decision$ or option$ or choice$)).ti,ab.
19 and 117
114 or 116 or 118
6 or 27 or 32 or 41 or 55 or 62 or 69 or 73 or 82 or 89 or 96 or 101 or 108 or 112 or 119
limit 120 to yr="1966 -Current"

Appendix C Quality assessment

	Criteria	Score ('Yes', 'No', 'Unclear', 'Not applicable (NA)')
1	Was the number of participants randomised stated?	
2	Was the method of randomisation adequate (e.g. use of random number table, computer random number generator, coin tossing, shuffling of cards or envelopes, throwing of dice)?	
3	Was allocation concealment adequate (e.g. central allocation, sequentially numbered opaque sealed envelopes)?	
4	Were the treatment groups comparable at baseline for important prognostic factors?	
5	If the above answer was no, was a suitable statistical method used to adjust for possible baseline imbalance?	
6	Was the study reported as being at least double blind?	
7	Were patients blinded?	
8	Were outcome assessors blinded?	
9	Were care givers blinded?	
10	Was intention-to treat analysis used (i.e. were all participants included in the analysis in the group to which they were allocated)?	
11	Were there any unexpected imbalances in drop outs between groups? If so, were they explained or adjusted for?	
12	Was selection/eligibility criteria adequately reported?	
13	Was the selected population representative of that seen in normal practice?	
14	Was an appropriate measure of variability reported?	
15	Was loss to follow-up reported or explained?	
16	Were at least 90% of those included at baseline followed up?	
17	Were patients recruited prospectively?	
18	Were patient recruited consecutively?	
19	Did the study report relevant prognostic factors?	

Case series quality rating

Good: the answer is 'yes' to criteria 12–19
Satisfactory: the answer is 'yes' to criteria 13 and 15–18
Poor: the answer is not 'yes' to one or more of the criteria listed for satisfactory

Feedback

The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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