Manuscript title:

Cost-effectiveness analysis of a placebo controlled randomised surgical trial evaluating the effectiveness of arthroscopic subacromial decompression in patients with subacromial shoulder pain (CSAW)

List of Authors:
Rombach, Ines[1, 2]; DPhil
Merritt, Naomi[2]; BSc
Shirkey, Beverly A[2]; PhD
Rees, Jonathan L[2] ; FRCS (Tr&Orth)
Cook, Jonathan A[2]; PhD
Cooper, Cushla[2]; MSc
Carr, Andrew J[2]; FRCS
Beard, David J*[2]; DPhil
Gray, Alastair M*[1]; PhD
*Authors Beard and Gray contributed equally.

1. University of Oxford, Health Economics Research Centre, Nuffield Department of Population Health, Oxford, UK
2. University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, UK

Corresponding author:
Ines Rombach, ines.rombach@ndorms.ox.ac.uk
Health Economics Research Centre
Nuffield Department of Population Health
University of Oxford
Richard Doll Building
Old Road Campus
Oxford OX3 7LF
UK
Phone: 0044 (0)1865 617911

Funding:
This study was funded by Arthritis Research UK (Clinical Studies Grant 19707), the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC; previously the Biomedical Research Unit), and the Royal College of Surgeons (England). The NIHR Oxford BRC is based at the Oxford University Hospitals NHS Foundation Trust and run in partnership with the University of Oxford, funded by the NIHR. The University of Oxford sponsored the study. JC held a Medical Research Council Methodology Fellowship (G1002292) for part of the duration of the study. The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences coordinated the study via the Surgical Intervention Trials Unit from the Royal College of Surgeons (England) Surgical Trials Initiative.
The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.
The views expressed in this report are those of the authors and do not necessarily reflect the views of the funders.

Key words:
Placebo surgery; cost-effectiveness analysis; health economics; quality adjusted life years; Subacromial decompression; shoulder impingement

Acknowledgements
This study was funded by Arthritis Research UK (Clinical Studies Grant 19707), the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC; previously the Biomedical Research Unit), and the Royal College of Surgeons (England). The NIHR Oxford BRC is based at the Oxford University Hospitals NHS Foundation Trust and run in partnership with the University of Oxford, funded by the NIHR. The University of Oxford sponsored the study. JC held a Medical Research Council Methodology Fellowship (G1002292) for part of the duration of the study. The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences coordinated the study via the Surgical Intervention Trials Unit from the Royal College of Surgeons (England) Surgical Trials Initiative.
We would like to thank the British Elbow and Shoulder Society for supporting and promoting this trial in the UK, all participants for their involvement in the study and the principal investigators and their teams at each of the CSAW sites. We acknowledge The Oxford Clinical Trials Research Unit, the National Institute of Health Research Clinical Research Network, and The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) for their support.
The views expressed in this paper are those of the authors and do not necessarily reflect the views of the funders.

Authors' contributions
DJB and AJC were co-chief investigators. JLR, CC and JAC were co-applicants on the grant application to Arthritis Research UK. IR and AG and were collaborators and were involved in the design of the study and its implementation. NM was the study co-ordinator. BAS, IR, and JAC performed the statistical analysis for the clinical paper. IR and AG were responsible for performing the analysis and writing the manuscript. All authors read and approved the final manuscript.

Data sharing:
Due to the confidential nature of some of the research materials supporting this publication not all of the data can be made accessible to other researchers. Please contact the corresponding author for more information.

Abstract:

Aims

The aims of this study were to compare the use of resources, costs and quality of life outcomes associated with subacromial decompression, arthroscopy only (placebo surgery) and no treatment for subacromial pain in the United Kingdom National Health Service, and to estimate their cost-effectiveness.

Patients and Methods

The use of resources, costs and quality-adjusted life years (QALYs) were assessed in the trial at six months and one year. Results were extrapolated to two years after randomisation. Differences between treatment arms, based on the intention-to-treat principle, were adjusted for covariates; missing data were handled using multiple imputation. Incremental cost-effectiveness ratios were calculated, with uncertainty around the values estimated using bootstrapping.

Results

Cumulative mean QALYs /mean costs of health care service use and surgery per patient from baseline to 12 months were estimated as 0.640 (standard error (SE) 0.024)/ £,3147 (SE 166) in the decompression arm, 0.656 (SE 0.020)/ £2830 (SE 183) in the arthroscopy only arm and 0.522 (SE 0.029)/ £1,451 (SE 151) in the no treatment arm. Statistically significant differences in cumulative QALYs and costs were found at six and 12 months for the decompression vs. no treatment comparison only.

The probabilities of decompression being cost-effective compared with no treatment at a willingness-to-pay threshold of £20,000 per QALY were close to 0% at six months and approximately 50% at one year, with this probability potentially increasing for the extrapolation to two years.

Discussion

The evidence for cost-effectiveness at 12 months was inconclusive. Decompression may be cost-effective in the longer-term, but results of this analysis are sensitive to the assumptions made about how costs and QALYs are extrapolated beyond the follow-up of the trial.

Key messages:

1. What is already known about the topic?

Arthroscopic subacromial decompression is a commonly performed surgery in patients with subacromial pain, but recent research demonstrated no clinical benefit of decompression surgery compared to arthroscopy only or no treatment.

2. What does the paper add to existing knowledge?

This study is the first to assess the cost-effectiveness of subacromial decompression compared to arthroscopy only and to no treatment.

3. What insights does the paper provide for informing health care-related decision making?

This research adds comparative evidence on the costs and quality of life of these procedures. It shows that decompression is significantly more costly than no treatment over 12 months, with no clear evidence that it is cost-effective. Further evidence on longer-term outcomes and costs is still required, as in some projected scenarios decompression could be cost-effective depending on how costs and QALYs are extrapolated beyond the trial follow-up.

The clinical results of the CSAW Trial[1,2] (Can Shoulder Arthroscopy work; ISRCTN 33864128) were recently published. This randomised controlled trial (RCT) aimed to address uncertainties about the most appropriate treatment for patients with subacromial pain in the shoulder. This common condition[3] is associated with significant impairment of quality of life and a substantial socioeconomic burden[4]. The trial investigated the mechanism by which surgical decompression[5] might benefit patients, and the effectiveness of this treatment. The aims were addressed by comparing the clinical and cost-effectiveness of arthroscopic subacromial decompression (short: decompression), arthroscopy only (diagnostic investigative arthroscopy and thus the surgery without removal of the tissue and bone spur) and no treatment. Crucially, the arthroscopy only arm was included to investigate the mechanisms of decompression by comparing decompression with arthroscopy only. Arthroscopy only has never been suggested as routine curative treatment for subacromial pain.

The patients were followed-up for 12 months after randomisation, with the primary endpoint of clinical effectiveness being assessed at six months. Full details of the study are reported elsewhere[1], and the patient reported outcome measures (PROMs) and clinical results have been published[2]. The primary analysis used the patients as they were randomised, regardless of compliance using the intention to treat (ITT) principle, and failed to show a clinically or statistically significant difference between the decompression and arthroscopy only arms, as measured by the Oxford Shoulder Score (OSS)[6], which was the primary outcome measure of this RCT. The clinically meaningful difference was defined as 4.5 points, and the mean difference for decompression vs. arthroscopy only was -1.3 (95% CI -3.9 to 1.3). A small statistically, but not clinically, significant improvement was found for both surgical groups compared with the no treatment group, with differences still evident at the one-year follow-up. A recent study from Finland[7] had a similar design but included exercise therapy instead of a no treatment arm. Their primary endpoint was pain in the shoulder measured on a visual analogue scale at 24 months, and the results were consistent with the CSAW trial in that no benefit of decompression over arthroscopy was found. No cost-effectiveness analysis has been reported for this trial.

The aim of this further study was to compare health related quality of life (QoL), the use of resources and costs associated with decompression, arthroscopy only and no treatment for the 313 patients in the CSAW trial. To our knowledge, this is the first trial to assess the cost-effectiveness of subacromial decompression compared with arthroscopy only and with no treatment.

Patients and Methods

The CSAW trial randomised patients from 30 centres in the United Kingdom between 2012 and 2015, allocating them to one of three options for the management of subacromial pain: subacromial decompression, arthroscopy only and no treatment. Randomisation was minimised by site, age (< 40, 40-55, 56+ years), gender and baseline OSS (< 19, 19-26, 27-33, 34+ points). The target sample size was 300 patients (100 per arm), based on the primary clinical endpoint, the OSS. Inclusion criteria involved subacromial pain for at least three months, no evidence of rotator cuff tears, patients who had completed a non-operative management programme, had at least one steroid injection and were eligible for surgery. Additional details on the inclusion and exclusion criteria and sample size calculation can be found in the protocol.[1]

The primary outcome of the health economics analysis was the incremental cost per quality-adjusted life year (QALY) gained, based on EQ-5D-3L responses during the 12-month follow-up. QALYs combine information about QoL and time. One QALY signifies one year of life in perfect health, and lower values indicate a lower Qol and/or death during that year. We focused on decompression vs. no treatment and decompression vs. arthroscopy only. The arthroscopy vs. no treatment comparison is reported for completeness in an appendix, but is omitted from the main analysis as arthroscopy was offered only in the context of a randomised experiment to control for any surgical placebo effect, and is not considered a valid routine form of treatment for these patients. The analysis was undertaken in the United Kingdom's NHS healthcare system. The time horizon was the duration of the CSAW trial, thus to one-year after randomisation with data collection at six months and one year, with additional longer-term extrapolation of data to two years post randomisation.

Data collection and attribution of costs

The costs of the initial surgical procedures were calculated as a sum of equipment costs, which were obtained from manufacturer's list prices, using a 15% discount, costs per minute for the time each patient spent in the operating theatre, and a minimal surgical procedure cost for shoulder procedures (day cases), intended to cover other items related to a surgical admission such as administrative processing, work-up and recovery. The small number of subsequent operations (two) and adverse events (nine) were not costed separately, but treated as included in the resources which were used during follow-up. Unit costs for the use of resources for the year 2015/16 were obtained from national unit costs (Supplementary Table I) and applied to all components.

The following details on the use of resources were collected for each patient: the type of initial procedure (decompression, arthroscopy only, rotator cuff repair (RCR) and 'other', including a mixture of intermediate and major procedures) was collected from the theatre form for all patients who underwent a surgical procedure within the trial, and the total time in the operating theatre for each patient. Details of the main equipment required for each procedure were identified in discussion with the trial team. The use of resources during follow-up including the number of GP and nurse visits, attendance to A&E departments, orthopaedic and other outpatient clinics and day hospitals, NHS physiotherapy appointments and overnight inpatient stays, were collected at six and 12 months after randomisation.

Health-related QoL was measured at baseline, and at six and 12 months after randomisation using the EQ-5D-3L. Utility scores were calculated from responses using Stata's 'eq5d' command[8], using the United Kingdom population tariff[9,10]; index scores of 1 indicate full health, 0 represents states equal to death, and negative values indicate states considered worse than death. QALYs for each patient were calculated using an area under the curve (AUC) approach after linear interpolation between time points.

Cost-effectiveness analyses

All analyses were conducted in Stata/SE 14 (StataCorp. LP, College Station, Texas). In the primary analysis, outcomes were analysed as randomised, regardless of compliance with the randomised procedure (intention to treat (ITT) approach). Imputation of missing data allowed for the inclusion of all randomised patients. Supplementary analyses included a per-protocol analysis, restricted to those who had received only their allocated intervention at 12 months, a complete cases analysis (including only those who had no missing observations for any utility or health resource use) and sensitivity analyses for unit costs.

Descriptive statistics (mean and standard errors (SE)) for the use of resources and related costs were calculated by treatment arm. Differences between treatment arms were adjusted for the minimisation factors, i.e. linear regression models were adjusted for gender, age and baseline OSS (used as continuous variables), while also adjusting for clustering within trial site using the 'cluster' option within Stata's regression command. Differences in health-related QoL and QALYs were adjusted for baseline EQ-5D-3L values instead of OSS baseline values. 95% confidence intervals and 5% significance levels were used throughout.

A cost-utility analysis was performed for three different time horizons. An analysis covering the six months following randomisation was conducted to align with the primary analysis of the trial[2]. A one-year analysis covered the entire follow-up period, and an analysis to 24 months after randomisation was undertaken to explore cost-effectiveness using some minimal assumptions concerning longer-term effects beyond the period of follow-up. Incremental cost-effectiveness ratios (ICER) were calculated as the incremental cost per QALY gained for each treatment comparison. Uncertainty around the ICERs was represented by 1,000 nonparametric bootstrapped replicates of the differences in mean total cost and QALY between the groups, which were then used to plot cost-effectiveness planes and to calculate the probability of one treatment arm being cost-effective at £20,000 per QALY against its comparator.

The following assumptions were made for the extrapolation to two years after randomisation: differences in QoL between the treatment arms were assumed to remain constant after 12 months, while no differences were assumed in mean costs between different treatment arms after the one-year follow-up point. Further analyses considered a scenario in which costs incurred over the six- to

12-month period continued to be incurred at the same rate during the following year by each patient. Both cost and QoL outcomes beyond one year of follow-up were discounted at an annual rate of 3.5%, in line with current recommendations[12].

Analyses of sensitivity examined the effect of different discounts in price being applied to the manufacturers' list prices (i.e. 0% and 30% instead of 15%).

Missing data were handled as follows: where patients had partly completed information about the use of resources, but had left some items unanswered, it was assumed that these health care resources were not used within the relevant follow-up period. Where patients had not answered any questions about the use of resources or given any EQ-5D-3L data, or the follow-up form was missing, multiple imputation by chained equations (MICE) was used[11]. Missing data for health-related QoL and use of resources at baseline (EQ-5D-3L only) six and 12 months after randomisation were imputed simultaneously using linear regression models and a predicted mean matching approach, imputing observed values from the pool of the five data points with the most similar predictive values[11]. Additional independent variables included in the imputation model included baseline OSS and EQ-5D-3L index, baseline use of resources, gender, age at randomisation and the initial surgery which was undertaken. Imputations were run separately by treatment arm. A total of 20 sets of imputed values were obtained using Stata's 'mi impute' command, and combined with the 'mi estimate' command to account for uncertainty around the imputations. Information about employment and change in employment during the study, the number of sick days and out-of-pocket expenses were summarised descriptively and are reported in the supplementary material.

Results

A total of 313 patients were randomised, 106 allocated to decompression, 103 to arthroscopy only and 104 to no treatment. The baseline characteristics of the groups were well balanced. The mean age of the patients at the time of entering the trial was 53.3 years (SD 10.3), 158 (50.5%) were female, and the mean OSS was 25.8 (SD 8.5).

The randomised intervention was received by 75%, 67% and 76% of patients in the decompression, arthroscopy only and no treatment arms, respectively. Additional details about the initial procedures received in each treatment arm (used to generate average total surgery costs) and the numbers included in the per-protocol and the complete cases analyses are shown in Table I.

Table I. Overview of the randomised patients, initial procedures and the numbers included in the analyses

	Randomised arm		
	Decompression	**Arthroscopy only**	**No treatment**
Total number randomised	106	103	104
Initial procedures			
Decompression	**80 (75%)**	3 (3%)*	18 (17%)
Arthroscopy only	0 (0%)	**69 (67%)***	0 (0%)
Rotator cuff repairs[1]	5 (5%)	4 (4%)	1 (1%)
Other shoulder surgery	4 (4%)	4 (4%)	6 (6%)
No surgery	17 (16%)	23 (22%)	**79 (76%)****
Populations analysed			
Included in the intention-to-treat population[2]	106 (100%)	103 (100%)	104 (100%)
Included in per-protocol population[3]	80 (75%)	68 (66%)*	78 (75%)**
Included in complete cases analysis[4]	81 (76%)	86 (83%)	79 (76%)

Numbers of patients who received their randomised procedures are highlighted in bold. There are two differences between this information and the details provided in the CSAW CONSORT flow diagram shown in the main clinical paper: One participant allocated to 'arthroscopy only' was listed as having received 'decompression' in the main clinical paper at 12 months. However, the decompression was their second operation; arthroscopy only was initially performed as categorised here. They are not included in the per-protocol population(*). One participant allocated to the 'no treatment' group was listed as withdrawn in the main clinical paper. They did not have surgery until the point of withdrawal and they are listed as 'no surgery' in this summary for ease of presentation. They are excluded from the per-protocol population(**).

[1]*Most rotator cuff repairs included decompressions.*

[2]*All randomised participants were included in the intention-to-treat population. Missing data were imputed.*

[3]*The per-protocol population includes all participants who received their allocation intervention, and none of the other trial interventions by 12 months post randomisation. Numbers included in this per-protocol population may differ from those in the main clinical paper as this analysis does not exclude additional participants due to missing outcome data.*

[4]*The complete cases analysis includes all participants who had no missing observations for any utility or health resource use over the 12 months follow-up. The numbers included in this complete cases analysis are different from those in the main clinical paper, which focussed on participants with available Oxford Shoulder Score data.*

The rates of returns of the questionnaire were high; 100% of baseline questionnaires, 88% at six months and 85% at 12 months were received. For a small number of additional patients (up to 4% overall), information on the use of resources and EQ-5D-3L was missing completely. The type of procedure was available for all patients who underwent surgery within the period of follow-up. Total times in the operating theatre were missing for three patients (one randomised to decompression, two to no treatment), who all underwent a decompression; the mean time recorded for decompression was used for these patients.

Costs and resource use for the initial trial procedures and follow-up

The volume and cost of resources for the initial procedures and during follow-up are summarised in Table II, with full details in Supplementary Table II.

Table II. Overview of the use of resources and costs by arm of the trial

	Decompression mean cost in £ (SE) n=106	Arthroscopy only mean cost in £ (SE) n=103	No treatment mean cost in £ (SE) n=104	Decompression *vs* Arthroscopy only: mean cost difference in £ (95% CI; p-value)	Decompression *vs* no treatment: mean cost difference in £* (95% CI; p-value)
Total surgery cost	1,767 (83)	1,299 (81)	536 (95)	461 (274 to 649; p < 0.001)**	1,231 (955 to 1,508; p < 0.001)**
Costs of health service use from baseline to 6 months (including initial trial procedure where relevant)	2,571 (113)	2,287 (144)	1,008 (120)	266 (-135 to 666; p = 0.184)	1,563 (1,169 to 1,956; p < 0.001)**
Costs of health service use from 6 to 12 months	577 (130)	543 (84)	443 (58)	15 (-256 to 286; p = 0.911)	129 (-148 to 406; p = 0.346)
Costs of health service use & surgery from baseline to 12 months	3,147 (166)	2,830 (183)	1,451 (151)	281 (-142 to 703; p = 0.183)	1,691 (1,216 to 2,167; p < 0.001)**

**Differences are adjusted for baseline Oxford Shoulder Score, age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*
***Statistically significant differences are highlighted.*
Abbreviations: CI – Confidence interval; SE – Standard error

The mean time in the operating theatre per patient, and hence costs for this time, and basic costs of the procedure differed significantly between all three treatment arms. The total mean costs of surgery per patient were highest in the decompression arm (£1,767, SE 83), followed by the arthroscopy only arm (£1,299, SE 81) and lowest in the no treatment arm (£536, SE 95); these differences were statistically significant.

During the follow-up from baseline to six months, differences in the use of resources and costs between treatment arms were seen for NHS physiotherapy appointments, day hospital admissions and inpatient nights. Costs for health services use during this time including the cost of the initial procedure were: decompression: £2,571 (SE 113), arthroscopy only: £2,287 (SE 144) and no treatment (£1,008, SE 120). Costs in the decompression arm were significantly higher than for no treatment ($p < 0.001$), but no significant differences were seen between the decompression and arthroscopy only arms ($p = 0.184$).

The use of health services and costs between six and 12 months follow-up were similar across treatment arms. The combined costs of surgery and health service use during the follow-up to 12 months were £3,147 (SE 166) in the decompression arm, £2,830 (SE 183) in the arthroscopy only arm and £1,451 (SE 151) in the no treatment arm. Decompression had significantly higher costs than no treatment ($p < 0.001$); costs in the decompression arm were not significantly different from those in the arthroscopy only arm ($p = 0.183$).

Quality of life outcomes

Information on QoL is presented in Table III. Improvements from baseline to six and 12 months were seen in all groups. Adjusted mean differences between the decompression and no treatment group were statistically significant at six months ($p = 0.007$). There were no statistically significant differences between decompression and arthroscopy only at six or 12 months (six months $p = 0.954$, 12 months $p = 0.397$).

Table III. Quality of life and quality adjusted life years (QALY)

QoL	Decompression Mean (SE) n=106	Arthroscopy only Mean (SE) n=103	No treatment Mean (SE) n=104	Decompression vs. Arthroscopy only* Mean (95% CI; p-value)	Decompression vs. no treatment* Mean (95% CI; p-value)
EQ-5D-3L Index at Baseline	0.517 (0.029)	0.553 (0.028)	0.499 (0.032)		
EQ-5D-3L Index at 6 Months	0.654 (0.030)	0.672 (0.027)	0.526 (0.036)	-0.002 (-0.086 to 0.081; p = 0.954)	0.120 (0.040 to 0.210; p = 0.007)**
EQ-5D-3L Index at 12 Months	0.735 (0.030)	0.728 (0.027)	0.658 (0.034)	0.027 (-0.038 to 0.093; p = 0.397)	0.080 (-0.010 to 0.160; p = 0.065)
QALYs					
QALYs baseline to 6 months	0.293 (0.012)	0.306 (0.011)	0.256 (0.015)	-0.001 (-0.022 to 0.020; p = 0.954)	0.030 (0.010 to 0.050; p = 0.007)**
QALYs 6 to 12 months	0.347 (0.013)	0.350 (0.011)	0.296 (0.015)	0.006 (-0.025 to 0.038; p = 0.683)	0.050 (0.020 to 0.080; p = 0.003)**
QALYs baseline to 12 months	0.640 (0.024)	0.656 (0.020)	0.552 (0.029)	0.006 (-0.045 to 0.056; p = 0.819)	0.080 (0.030 to 0.130; p = 0.002)**
QALYs baseline to 2 years**	1.349 (0.050)	1.359 (0.043)	1.188 (0.056)	0.032 (-0.072 to 0.136; p = 0.528)	0.160 (0.040 to 0.270; p = 0.008)**

**Differences are adjusted for baseline EQ-5D-3L index, age at the time of randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*
The summaries in this table include all patients. Missing data were handled using multiple imputation by chained equations.
***Statistically significant differences are highlighted.*
Abbreviations: CI – Confidence interval; QALY – Quality-adjusted life year QoL – Quality of life; SE – Standard error.

Information about the QALYs are also shown in Table III. The adjusted difference in QALYs during one year follow-up between the decompression and arthroscopy only arms was not significant. The mean QALYs in the no treatment arm over the 12 month follow-up was significantly lower compared with the decompression arm ($p = 0.002$). The QALYs from baseline to six months, six to 12 months and baseline to two years were also significantly higher in the decompression arm compared with the no treatment arm, but no significant differences were found between the decompression and arthroscopy only arms.

Incremental cost-effectiveness

The results from the incremental cost-effectiveness are shown in Table IV (Supplementary Table IV also shows the cost-effectiveness for the arthroscopy only arm). Significantly larger mean costs were associated with the decompression arm compared with the no treatment group, while differences in QALYs are small at the six-month follow-up and moderate at 12 months. A cost-effectiveness plane (Fig. 1, also Supplementary Figure a) shows the uncertainty around the estimates at 12 months. On the cost-effectiveness plane, higher values on the vertical axis indicate higher differences in cost and points further to the right on the horizontal axis indicate a larger difference in QALYs for decompression compared with its comparators. Points that fall below the dashed line are cost-effective at a £20,000 per QALY willingness-to-pay threshold. The probability of decompression being cost-effective at a £20,000 per QALY compared with no treatment is close to 0% at six months and 50% at 12 months. Extrapolating to two years after randomisation, the probability of decompression being cost-effective compared with no treatment at £20,000 per QALY increases to between 84% and 89% for decompression, depending on the assumptions made in the extrapolation.

Table IV. Incremental cost-effectiveness

	Analysis and comparison	**Difference in costs (£)* Mean (95% CI; p-value)**	**Difference in QALYs* Mean (95% CI; p-value)**	**Mean incremental cost per QALY gained**	**More effective**	**Less costly**	**Cost-effective at £20,000 per QALY gained**
Baseline to 6 months	Decompression *vs* no treatment	1,563 (1,169 to 1,956; p < 0.001)	0.030 (0.010 to 0.050; p = 0.007)	52,100 (NE quadrant)	*100%*	*0%*	*0%*
	Decompression *vs* arthroscopy only	266 (-135 to 666; p = 0.184)	-0.001 (-0.022 to 0.020; p = 0.954)	-266,000 (NW quadrant)	*53%*	*16%*	*23%*
Baseline to 12 months	Decompression *vs* no treatment	1,691 (1,216 to 2,167; p < 0.001)	0.080 (0.030 to 0.130; p = 0.002)	21,138 (NE quadrant)	*100%*	*0%*	*50%*
	Decompression *vs* arthroscopy only	281 (-142 to 703; p = 0.183)	0.006 (-0.045 to 0.056; p = 0.819)	46,833 (NE quadrant)	*63%*	*17%*	*46%*
Baseline to two years (extrapolation scenario 1)	Decompression *vs* no treatment	1,691 (1,216 to 2,167; p < 0.001)	0.160 (0.040 to 0.270; p = 0.008)	10,569 (NE quadrant)	*100%*	*0%*	*89%*
	Decompression *vs* arthroscopy only	281 (-142 to 703; p = 0.183)	0.032 (-0.072 to 0.136; p = 0.528)	8,781 (NE quadrant)	*76%*	*17%*	*70%*
Baseline to two years (extrapolation scenario 2)	Decompression *vs* no treatment	1,940 (1,046 to 2,834; p < 0.001)	0.160 (0.040 to 0.270; p = 0.008)	12,125 (NE quadrant)	*100%*	*0%*	*84%*
	Decompression *vs* arthroscopy only	309 (-484 to 1,103; p = 0.428)	0.032 (-0.072 to 0.136; p = 0.528)	9,656 (NE quadrant)	*76%*	*24%*	*67%*

**Differences are adjusted for baseline Oxford Shoulder Score (costs)/ baseline EQ-5D-3L index, age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*
Extrapolation scenario 1: Carry forward QoL from 12 months; assume no differential costs between the treatment arms
Extrapolation scenario 2: Carry forward QoL from 12 months; also carry over cost observed from 6-12 months for each additional six month period
Abbreviations: CI – Confidence interval; NE – North-east quadrant of the cost-effectiveness plane; NW – North-west quadrant of the cost-effectiveness plane; QALY – Quality-adjusted life year; QoL – Quality of life.

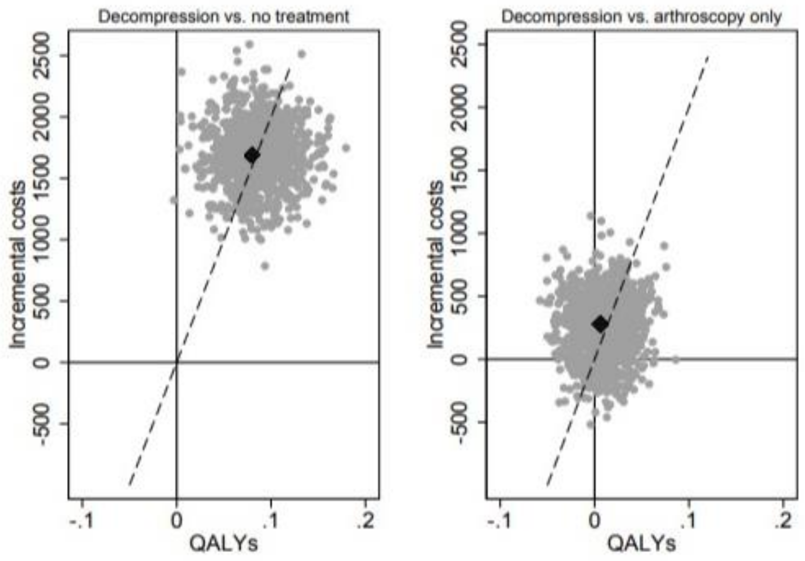

Figure 1. Cost-effectiveness planes, baseline to 12 months.
Note: Points that fall below the dashed line are cost-effective at a £20,000 per QALY willingness-to-pay threshold. Abbreviations: QALY – Quality adjusted life year.

Decompression had similar QoL outcomes to arthroscopy only at six months, but slightly higher outcomes at 12 months (adjusted differences), while being a mean of £266 and £281 more expensive at six and 12 months, respectively. The probability of decompression being more cost-effective than arthroscopy only at £20,000 per QALY at six and 12 months was 23% and 46%, respectively. At two years post randomisation, the probability of decompression being cost-effective at £20,000 compared with arthroscopy only is between 67% and 70%, depending on the assumptions made in the extrapolation.

The results from the per-protocol, the complete cases analyses and scenarios considering 0% and 30% price discounts are consistent with these findings with little evidence of cost-effectiveness at a £20,000 per QALY gain threshold (Supplementary Tables V and VI). The probability of decompression being cost-effective at £20,000 per QALY compared with no treatment or arthroscopy only using the per-protocol population is 0% and 8%, respectively at six months after randomisation, and 12% and 49% at 12 months after randomisation. By excluding patients who did not receive their allocated procedure in the per-protocol analysis, the differences in mean costs are more pronounced between the decompression and no treatment arms. The changes in these differences are driven by the costs of the procedures. Using the complete cases analysis, the probability of decompression being cost-effective at £20,000 per QALY compared with no treatment or arthroscopy only is 0% and 7%, respectively at six months after randomisation, and 44% and 31% at 12 months after randomisation.

Sensitivity analyses examining the effect of other discounts applied to surgical equipment (0% and 30% instead of a 15% discount as used in the primary analysis) had little effect on the differences in cost between treatment arms, as well as the ICERs generated, and produced similar results to the primary analysis. The effects of the change in discounts were diluted by non-compliance to the randomised intervention. Thus, the mean cost per patient changed by approximately £80, £44 and £23 in the decompression, arthroscopy only and no treatment arms at 12 months, respectively, with increases of this amount seen for a decrease in discount to 0%, and a decrease of this amount observed for an increase in discount to 30%. These differences were small compared with the overall costs per patient in each treatment arm, and thus decompression remained significantly more expensive than no treatment. The difference in costs between decompression and arthroscopy only remained non-significant. The probability of decompression being cost-effective compared with no treatment at one year remained similar to that reported for the primary analysis.

<u>Employment and out-of-pocket expenses</u>

There was no evidence of significant differences in employment, change in employment, number of sick days (Supplementary Tables VII, VIII and IX), use of additional over the counter medication, private practitioners and exercise equipment or activities (Supplementary Table X), or costs incurred by the patient, including money spent on additional over the counter medication, private practitioners and exercise equipment or activities (supplementary Table XI) between the treatment arms.

Discussion

We found that randomisation to decompression was associated with significantly higher costs during a one-year follow-up than randomisation to no treatment (mean difference £1,691, 95% CI £1,216 to £2,167). These differences were mainly due to the operation, and to a lesser extent to an increased health service use, particularly the use of physiotherapists, admissions to day hospitals and inpatient nights during the first six months of follow-up. We found no significant differences in costs between the decompression and arthroscopy arms during the 12 months' follow-up. At six months after randomisation, self-reported QoL was significantly higher in both surgery arms compared with no treatment, but not significantly different between those randomised to decompression and arthroscopy only. There were no significant differences in QoL at the end of the 12-month follow-up period, although those in the decompression arm had a marginally higher mean EQ-5D-3L value than those in the arthroscopy only arm. Similar trends were observed for other PROMs recorded in the CSAW trial.[2]

For both decompression *vs.* no treatment and decompression *vs.* arthroscopy only there is an approximately 50% chance of being cost-effective at £20,000 per QALY gained at the end of the one-year follow-up. Extrapolating the outcomes to two years after randomisation, in particular assuming that small differences in QoL at 12 months persist to 24 months, had a large effect on the results, increasing the probability of decompression *vs* no treatment and decompression *vs* arthroscopy only being cost-effective. However, no long-term data are available on these patients, and it is not known how realistic these assumptions are.

This cost-effectiveness analysis was conducted alongside a RCT which recruited patients from 30 hospitals in the United Kingdom, and so is broadly based and had low levels of loss to follow-up and missing data. However, it has limitations. First, information on actual discounts offered to hospitals for surgical equipment is hard to obtain, and so the same level of discount was assumed across all sites. However, analyses of sensitivity examining different levels of discounts did not greatly alter the results. Secondly, not all patients received their randomised procedure. Between 24% and 33% of patients were treated with other or additional procedures. The costs therefore incorporate a mixture of procedures and the results should be interpreted as an ITT analysis. Thirdly, the analysis was performed from the perspective of the health care system alone, and information about wider societal costs such as time off work, and out-of-pocket expenses which were incurred by patients was only summarised descriptively, and is reported as supplementary material. Finally, the maximum duration of follow-up was 12 months, which may not have been long enough to capture longer-term effects of the procedures with respect to costs and particularly QoL. A simple extrapolation over a short period of an additional 12 months and using highly restrictive assumptions nevertheless had a large effect on the estimates of cost-effectiveness.

In the CSAW trial, arthroscopy only was only offered as part of the randomised experiment to control for any surgical placebo effect. The results from a cost-effectiveness analysis of a comparison between arthroscopy only *vs.* no treatment are not easily interpretable, since, even if shown to be cost-effective, the arthroscopy only procedure could not be used in these patients. We have not discussed these results in this paper, although they are shown in the supplementary material.

In conclusion, this study shows no evidence that decompression is cost-effective during the one-year follow-up period. It may be cost-effective in the long-term, but results of this analysis are sensitive to the assumptions made about how costs and QALYs are extrapolated beyond the follow-up of the trial. Studies with longer-term follow-up are needed.

Supplementary material

Tables and figures showing unit costs, detailed information on resource use, costs, QoL are provided in the supplementary material. Incremental cost-effectiveness for the sensitivity analyses at 6 and 12 months post randomisation (per-protocol and complete case analysis, variation in price discounts), and adjusted differences between the arthroscopy only and no treatment arm are also presented. Cost-effectiveness planes for all comparisons covering time from randomisation to 12 months and for the extrapolation to 24 months are included. Tables summarising employment and change of employment information, sick days, use of additional over the counter medication, use of private practitioners and monies spent on exercise equipment or activities are presented. …

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Supplementary material

Cost-effectiveness analysis of a placebo controlled randomised surgical trial in patients with shoulder pain (CSAW) – SUPPLEMENTARY MATERIAL

Supplementary material Table I: Unit costs

Cost category	Unit cost	Source and description
Cost per minute in theatre	£17.25 per minute (£1035 per hour)	Mean cost per minute in an orthopaedic operating theatre. Average over 15 NHS boards in Scotland, data released November 2016. Information Science Division Scotland National Statistics release 17 December 2016.
Cost of minimal procedure	£554	National average cost for minimal shoulder procedure for Non-Trauma day cases. Obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "Day Case" tab.
Additional equipment costs for surgeries performed – main cost drivers only		
Anchors (cost per anchor in arthroscopic repair)	£145.70	Manufacturer's list price, obtained in 2012/13, adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16. Only RCRs – use average number used in UKUFF (1.2 in arthroscopic arm)
Drapes	£24.22	All surgeries UKUFF: Manufacturer's list prices for shoulder arthroscopy drape and video camera drape. Adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16.
Fluid management system on day tubing	£30.97	All surgeries UKUFF: Manufacturer's list price Adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16.
Radio frequency electrode	£132.86	Only ASAD UKUFF: Hospital costs, adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16.
Full radius soft tissue resector	£84.90	Only ASAD UKUFF: Manufacturer's list price Adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16.
Oval bone burr	£84.90	Only ASAD UKUFF: Manufacturer's list price Adjusted by Hospital and Community Health Service (HCHS) pay and prices inflation index to account for change in costs between 2012/13 and 2015/16.
Sling (one sling per operation)	£19.31 (£13.08 including VAT)	All surgeries Hospital cost obtained (2007, discounting applied)
Costs of shoulder procedures (to cover	Cost per shoulder	Generally, AO and ASAD are classed as intermediate procedures, RCR is classed as a major procedure. The "other"

admissions before surgery and recovery time after surgery)	procedure for non-trauma with CC score 0-1: Major: £2473 Intermediate: £1966 Minor: £1470 Weighted average minor/intermediate: £1778	procedures were a mixture between intermediate and major procedures. However, in order to avoid double-counting of surgical costs, as theatre time and equipment cost are added separately, the procedures will be costed at the next lower level of complexity (i.e. ASAD, usually seen as an intermediate procedure is costed as a minor shoulder procedure etc.). As such, these estimates are used to cover admission and general hospital costs, while the main cost drivers for the procedures are costed separately, to more adequately reflect cost drivers and differential costs between the procedures. (Note: the mean cost for each procedure calculated as described above were found similar to patient surgery costs for the relevant procedures obtained in an audit at the NOC.) National average unit cost, obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "DC" tab.
Hospital visits		
Seen in A&E	£146.86	National average unit cost, obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "Total outpatients attendance" tab.
Orthopaedic outpatient clinic	£117.01	National average unit cost for trauma and orthopaedics outpatient attendances, obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "Total outpatients attendance" tab. *(not restricted to shoulder – in line with the way question is posed)*
Other hospital outpatient clinic	£124.69	National average unit cost, calculated as the weighted average of all outpatient attendances other than A&E, physiotherapy and orthopaedic outpatient clinics. Obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "Total outpatients attendance" tab.
Visits to NHS physio	£48.33	National average unit cost, obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "Total outpatients attendance" tab.
Number of admissions to day hospital	£730.30	Weighted average of all day cases, excluding paediatric cases and cases related to ante-natal, neonatal or fertility related admissions. Obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "DC" tab.
Inpatient episodes (unit cost per night spent in hospital)	£613.11	Weighted average of elective inpatient, non-elective inpatients and non-elective short stay costs per days, excluding paediatric cases and cases related to ante-natal, neonatal or fertility related admissions. Obtained from the National Schedule of Reference Costs – Year 2015-16 file "The main schedule", "EL", "NEL", "NES" tabs.
GP visists		
GP	£33.32	Personal Social Services Research Unit (PSSRU) unit costs of health and social care 2016, table 10.3b. Average consultation

		lasting 9.22 minutes, excluding direct care staff costs and including qualification costs: £33 Home visits were not covered in the 2016 version of the document. 2013 document, out of surgery visits, including travel time and longer visit durations, cost approximately 2.5 times as much as GP patient contacts in surgery. This factor will be applied to GP in surgery visits to estimate the costs of GP home visits in this trial. In CSAW (baseline, 6 months and follow-up) there were 1971 in surgery GP visits and 13 GP home visits. GP costs per visit are calculated as a weighted average of GP visits in surgery vs. at home visits.
Nurse	Band 4: £7.89 per consultation	Personal Social Services Research Unit (PSSRU) unit costs of health and social care 2016, table 10.6. £29 per hour for band 4) → £7.49 (£36 per hour for band 5) Average consultation lasting 15.5 minutes – referenced in PSSRU 2015 (Based on the 2006/07 UK general practice survey). The cost for home visits is calculated as described for GPs above. In CSAW, there were 15 nurse home visits and 637 nurse GP visits reported

Assumptions made:

- Staffing levels are the same for decompression and arthroscopy only, and are captured in costs of theatre time.
- Additional visits: post-surgery follow-up visits and the clinical assessment at three months in the AMSR arm are expected to be captured in the “number of visits to orthopaedic outpatient clinic” question on the follow-up questionnaires.
- All procedures are performed as day cases, with no overnight stays.

Supplementary Table II: Detailed summary of resource use and associated costs for all three trial arms

	Resource use (time in theatre, number of appointments etc.)						Cost based on resource use (in £)					
	Decompression mean (SE) (n=106)	Arthroscopy only mean (SE) (n=103)	No treatment mean (SE) (n=104)	Decompression vs. Arthroscopy only mean difference* (96% CI, p-value)	Decompression vs. No treatment mean difference * (96% CI, p-value)	Arthroscopy only vs. No treatment mean difference * (96% CI, p-value)	Decompression mean cost in £ (SE) (n=106)	Arthroscopy only mean cost in £ (SE) (n=103)	No treatment mean cost in £ (SE) (n=104)	Decompression vs. Arthroscopy only mean cost difference in £ (96% CI, p-value)	Decompression vs. No treatment mean cost difference in £ * (96% CI, p-value)	Arthroscopy only vs. No treatment mean cost difference in £ * (96% CI, p-value)
SURGERY COSTS												
Total time in theatre (minutes)	50 (3)	37 (3)	16 (3)	13 (6 to 20; p<0.001)	34 (25 to 43; p<0.001)	21 (9 to 32; p<0.001)	859 (49)	633 (48)	277 (51)	225 (100 to 351; p<0.001)	583 (430 to 736; p<0.001)	359 (162 to 556; p<0.001)
Basic procedure costs							908 (39)	666 (37)	259 (45)	236 (150 to 322; p<0.001)	648 (512 to 784; p<0.001)	411 (291 to 532; p<0.001)
Total surgery cost							1,767 (83)	1,299 (81)	536 (95)	461 (274 to 649; p<0.001)	1,231 (955 to 1508; p<0.001)	770 (463 to 1078; p<0.001)
Baseline to 6 months												
GP appointments	2.30 (0.28)	2.13 (0.25)	1.90 (0.23)	0.11 (-0.69 to 0.90; p=0.780)	0.40 (-0.39 to 1.19; p=0.307)	0.26 (-0.49 to 1.01; p=0.475)	77 (9)	71 (8)	63 (7)	4 (-23 to 30; p=0.780)	13 (-13 to 40; p=0.307)	9 (-16 to 34; p=0.475)
Nurse appointments	0.83 (0.12)	0.65 (0.10)	0.72 (0.13)	0.16 (-0.09 to 0.41; p=0.190)	0.11 (-0.21 to 0.42; p=0.477)	-0.07 (-0.39 to 0.25; p=0.671)	7 (1)	5 (1)	6 (1)	1 (-1 to 3; p=0.190)	1 (-2 to 3; p=0.477)	-1 (-3 to 2; p=0.671)
Visits to A&E	0.08 (0.03)	0.11 (0.04)	0.13 (0.04)	-0.03 (-0.14 to 0.07; p=0.513)	-0.06 (-0.18 to 0.06; p=0.294)	-0.03 (-0.13 to 0.08; p=0.611)	11 (4)	16 (6)	20 (6)	-5 (-20 to 10; p=0.513)	-9 (-26 to 8; p=0.294)	-4 (-19 to 12; p=0.611)
Visits to Orthopaedic outpatient clinic	1.24 (0.12)	1.30 (0.15)	1.08 (0.12)	-0.10 (-0.55 to 0.34; p=0.631)	0.15 (-0.25 to 0.56; p=0.441)	0.23 (-0.24 to 0.71; p=0.318)	145 (14)	152 (18)	126 (14)	-12 (-64 to 40; p=0.631)	18 (-30 to 65; p=0.441)	27 (-28 to 83; p=0.318)
Visits to other hospital outpatient clinic	0.53 (0.11)	0.44 (0.10)	0.40 (0.09)	0.08 (-0.20 to 0.36; p=0.570)	0.13 (-0.10 to 0.36; p=0.250)	0.06 (-0.22 to 0.33; p=0.679)	66 (13)	55 (13)	50 (11)	10 (-25 to 45; p=0.570)	16 (-12 to 45; p=0.250)	7 (-27 to 41; p=0.679)
Visits to NHS physiotherapist	3.09 (0.38)	3.41 (0.66)	1.80 (0.36)	-0.37 (-2.13 to 1.40; p=0.674)	1.31 (0.14 to 2.48; p=0.030)	1.66 (-0.29 to 3.61; p=0.092)	150 (18)	165 (32)	87 (18)	-18 (-103 to 68; p=0.674)	63 (7 to 120; p=0.030)	80 (-14 to 174; p=0.092)
Admissions to day hospital	0.39 (0.05)	0.38 (0.05)	0.08 (0.03)	0.01 (-0.19 to 0.20; p=0.956)	0.31 (0.17 to 0.45; p<0.001)	0.30 (0.17 to 0.44; p<0.001)	282 (38)	277 (37)	57 (21)	4 (-138 to 146; p=0.956)	225 (122 to 327; p<0.001)	220 (121 to 318; p<0.001)
Inpatient nights	0.11 (0.05)	0.40 (0.15)	0.10 (0.06)	-0.29 (-0.52 to -0.07; p=0.013)	0.01 (-0.13 to 0.14; p=0.918)	0.30 (0.12 to 0.49; p=0.003)	67 (30)	246 (91)	63 (36)	-179 (-316 to -43; p=0.013)	4 (-78 to 86; p=0.918)	186 (73 to 300; p=0.003)

Costs of health service use from baseline to 6 months (excluding initial trial procedure where relevant)							803 (61)	988 (124)	472 (57)	-196 (-513 to 122; p=0.216)	331 (148 to 515; p=0.001)	525 (291 to 759; p<0.001)
Costs of health service use from baseline to 6 months (including initial trial procedure where relevant)							2,571 (113)	2,287 (144)	1,008 (120)	266 (-135 to 666; p=0.184)	1,563 (1169 to 1956; p<0.001)	1,295 (889 to 1701; p<0.001)
6 months to 12 months												
GP appointments	1.93 (0.25)	2.04 (0.22)	1.76 (0.24)	-0.16 (-0.85 to 0.53; p=0.630)	0.15 (-0.54 to 0.83; p=0.654)	0.29 (-0.40 to 0.97; p=0.394)	64 (8)	68 (7)	59 (8)	-5 (-28 to 18; p=0.630)	5 (-18 to 28; p=0.654)	10 (-13 to 32; p=0.394)
Nurse appointments	1.02 (0.17)	0.71 (0.15)	0.68 (0.17)	0.29 (-0.13 to 0.71; p=0.163)	0.35 (-0.15 to 0.84; p=0.163)	0.01 (-0.44 to 0.46; p=0.962)	8 (1)	6 (1)	5 (1)	2 (-1 to 6; p=0.163)	3 (-1 to 7; p=0.163)	0 (-3 to 4; p=0.962)
Visits to A&E	0.07 (0.03)	0.10 (0.03)	0.11 (0.04)	-0.04 (-0.12 to 0.05; p=0.394)	-0.04 (-0.12 to 0.05; p=0.377)	0.00 (-0.09 to 0.08; p=0.936)	10 (5)	15 (5)	16 (5)	-5 (-17 to 7; p=0.394)	-5 (-18 to 7; p=0.377)	0 (-13 to 12; p=0.936)
Visits to Orthopaedic outpatient clinic	0.56 (0.09)	0.71 (0.10)	0.75 (0.10)	-0.17 (-0.42 to 0.08; p=0.167)	-0.19 (-0.44 to 0.06; p=0.133)	-0.03 (-0.25 to 0.19; p=0.802)	65 (11)	83 (12)	87 (12)	-20 (-50 to 9; p=0.167)	-22 (-52 to 7; p=0.133)	-3 (-29 to 23; p=0.802)
Visits to other hospital outpatient clinic	0.48 (0.15)	0.37 (0.08)	0.42 (0.09)	0.09 (-0.15 to 0.34; p=0.435)	0.05 (-0.28 to 0.39; p=0.734)	-0.06 (-0.28 to 0.17; p=0.609)	60 (18)	46 (10)	53 (12)	12 (-19 to 43; p=0.435)	7 (-34 to 48; p=0.734)	-7 (-35 to 21; p=0.609)
Visits to NHS physiotherapist	2.21 (0.39)	2.25 (0.44)	1.37 (0.31)	-0.10 (-1.35 to 1.15; p=0.870)	0.83 (0.00 to 1.66; p=0.051)	0.91 (-0.21 to 2.04; p=0.106)	107 (19)	109 (21)	66 (15)	-5 (-65 to 56; p=0.870)	40 (0 to 80; p=0.051)	44 (-10 to 98; p=0.106)
Admissions to day hospital	0.12 (0.04)	0.10 (0.03)	0.09 (0.03)	0.02 (-0.06 to 0.11; p=0.583)	0.03 (-0.06 to 0.12; p=0.471)	0.00 (-0.05 to 0.06; p=0.867)	88 (28)	72 (23)	65 (21)	17 (-46 to 80; p=0.583)	22 (-40 to 84; p=0.471)	3 (-39 to 46; p=0.867)
Inpatient nights	0.28 (0.19)	0.23 (0.11)	0.15 (0.05)	0.03 (-0.40 to 0.47; p=0.882)	0.13 (-0.30 to 0.56; p=0.537)	0.08 (-0.17 to 0.33; p=0.510)	175 (114)	144 (68)	92 (30)	19 (-248 to 287; p=0.882)	80 (-184 to 344; p=0.537)	49 (-103 to 201; p=0.510)
Costs of health service use from 6 to 12 months							577 (130)	543 (84)	443 (58)	15 (-256 to 286; p=0.911)	129 (-148 to 406; p=0.346)	96 (-100 to 292; p=0.322)
Baseline to 12 months												
GP appointments	4.23	4.18	3.66	-0.05 (-1.24 to	0.55 (-0.68 to	0.55 (-0.64 to	141	139	122	-2 (-41 to 38;	18 (-23 to 59;	18 (-21 to 58;

	(0.44)	(0.39)	(0.39)	1.14; p=0.926)	1.77; p=0.362)	1.73; p=0.347)	(15)	(13)	(13)	p=0.926)	p=0.362)	p=0.347)
Nurse appointments	1.85 (0.23)	1.36 (0.19)	1.40 (0.25)	0.45 (-0.05 to 0.95; p=0.075)	0.46 (-0.17 to 1.08; p=0.143)	-0.06 (-0.63 to 0.51; p=0.842)	15 (2)	11 (2)	11 (2)	4 (0 to 7; p=0.075)	4 (-1 to 9; p=0.143)	0 (-5 to 4; p=0.842)
Visits to A&E	0.14 (0.05)	0.21 (0.05)	0.24 (0.06)	-0.07 (-0.19 to 0.06; p=0.274)	-0.10 (-0.26 to 0.06; p=0.227)	-0.03 (-0.15 to 0.09; p=0.616)	21 (7)	31 (8)	35 (8)	-10 (-28 to 8; p=0.274)	-14 (-38 to 10; p=0.227)	-4 (-22 to 13; p=0.616)
Visits to Orthopaedic outpatient clinic	1.79 (0.17)	2.01 (0.20)	1.83 (0.18)	-0.28 (-0.85 to 0.30; p=0.329)	-0.04 (-0.59 to 0.51; p=0.890)	0.21 (-0.38 to 0.80; p=0.475)	210 (19)	236 (24)	214 (21)	-32 (-100 to 35; p=0.329)	-4 (-69 to 60; p=0.890)	24 (-45 to 93; p=0.475)
Visits to other hospital outpatient clinic	1.01 (0.19)	0.82 (0.15)	0.82 (0.13)	0.17 (-0.23 to 0.57; p=0.379)	0.19 (-0.27 to 0.64; p=0.404)	0.00 (-0.38 to 0.38; p=1.000)	126 (24)	102 (18)	103 (17)	22 (-28 to 71; p=0.379)	23 (-33 to 80; p=0.404)	0 (-47 to 47; p=1.000)
Visits to NHS physiotherapist	5.31 (0.56)	5.66 (0.90)	3.18 (0.51)	-0.47 (-2.87 to 1.94; p=0.693)	2.14 (0.64 to 3.63; p=0.007)	2.57 (0.12 to 5.02; p=0.041)	256 (27)	274 (43)	153 (25)	-23 (-139 to 94; p=0.693)	103 (31 to 176; p=0.007)	124 (6 to 243; p=0.041)
Admissions to day hospital	0.51 (0.06)	0.48 (0.06)	0.17 (0.04)	0.03 (-0.18 to 0.23; p=0.779)	0.34 (0.18 to 0.50; p<0.001)	0.31 (0.18 to 0.43; p<0.001)	370 (45)	348 (41)	122 (29)	21 (-129 to 171; p=0.779)	246 (130 to 363; p<0.001)	223 (131 to 316; p<0.001)
Inpatient nights	0.39 (0.19)	0.64 (0.21)	0.25 (0.07)	-0.26 (-0.75 to 0.23; p=0.282)	0.14 (-0.29 to 0.57; p=0.516)	0.38 (0.05 to 0.72; p=0.026)	242 (118)	390 (127)	155 (45)	-160 (-460 to 140; p=0.282)	84 (-180 to 348; p=0.516)	235 (31 to 440; p=0.026)
Costs of health service use from baseline to 12 months (excluding initial trial procedure where relevant)							1,380 (147)	1,531 (168)	915 (90)	-181 (-567 to 206; p=0.343)	460 (139 to 781; p=0.007)	620 (330 to 911; p<0.001)
Costs of health service use & surgery from baseline to 12 months (including initial trial procedure where relevant)							3147 (166)	2830 (183)	1451 (151)	281 (-142 to 703; p=0.183)	1,691 (1216 to 2167; p<0.001)	1,391 (901 to 1881; p<0.001)

**Differences are adjusted for baseline Oxford Shoulder Score, age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command). Statistically significant differences are highlighted in grey. Statistically significant differences are highlighted in grey.Abbreviations: CI – Confidence interval; SE – Standard error*

Table III: Quality of life and quality adjusted life years (QALY), including comparisons between all three treatment arms

QoL	Decompression Mean (SE) n=106	Arthroscopy only Mean (SE) n=103	No treatment Mean (SE) n=104	Decompression vs. Arthroscopy only* Mean (95% CI; p-value)	Decompression vs. no treatment* Mean (95% CI; p-value)	Arthroscopy only vs. no treatment* Mean (95% CI; p-value)
EQ-5D-3L Index at Baseline	0.517 (0.029)	0.553 (0.028)	0.499 (0.032)			
EQ-5D-3L Index at 6 Months	0.654 (0.030)	0.672 (0.027)	0.526 (0.036)	-0.002 (-0.086 to 0.081; p=0.954)	0.120 (0.040 to 0.210; p=0.007)	0.116 (0.022 to 0.209; p=0.018)
EQ-5D-3L Index at 12 Months	0.735 (0.030)	0.728 (0.027)	0.658 (0.034)	0.027 (-0.038 to 0.093; p=0.397)	0.080 (-0.010 to 0.160; p=0.065)	0.047 (-0.034 to 0.128; p=0.238)
QALYs						
QALYs baseline to 6 months	0.293 (0.012)	0.306 (0.011)	0.256 (0.015)	-0.001 (-0.022 to 0.020; p=0.954)	0.030 (0.010 to 0.050; p=0.007)	0.029 (0.006 to 0.052; p=0.018)
QALYs 6 to 12 months	0.347 (0.013)	0.350 (0.011)	0.296 (0.015)	0.006 (-0.025 to 0.038; p=0.683)	0.050 (0.020 to 0.080; p=0.003)	0.041 (0.011 to 0.071; p=0.010)
QALYs baseline to 12 months	0.640 (0.024)	0.656 (0.020)	0.552 (0.029)	0.006 (-0.045 to 0.056; p=0.819)	0.080 (0.030 to 0.130; p=0.002)	0.070 (0.020 to 0.119; p=0.008)
QALYs baseline to 2 years**	1.349 (0.050)	1.359 (0.043)	1.188 (0.056)	0.032 (-0.072 to 0.136; p=0.528)	0.160 (0.040 to 0.270; p=0.008)	0.115 (0.009 to 0.221; p=0.035)

**Differences are adjusted for baseline EQ-5D-3L index, age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*

The summaries in this table include all randomised participants. Missing data was handled using multiple imputation by chained equations. Statistically significant differences are highlighted in grey. Statistically significant differences are highlighted.

Abbreviations: CI – Confidence interval; QALY – Quality-adjusted life year; QoL – Quality of life; SE – Standard error.

Supplementary Table IV: Incremental cost-effectiveness

	Analysis & comparison	Difference in costs (£)* Mean (95% CI; p-value)	Difference in QALYs* Mean (95% CI; p-value)	Mean incremental cost per QALY gained	More effective	Less costly	Probability of cost-effectiveness at £20,000 per QALY gained
Baseline to 6 months	Decompression vs. no treatment	1,563 (1169 to 1956; p<0.001)	0.030 (0.010 to 0.050; p=0.007)	52,100 (NE quadrant)	100%	0%	0%
	Arthroscopy only vs. no treatment	1,295 (889 to 1701; p<0.001)	0.029 (0.006 to 0.052; p=0.018)	44,655 (NE quadrant)	100%	0%	3%
	Decompression vs. arthroscopy only	266 (-135 to 666; p=0.184)	-0.001 (-0.022 to 0.020; p=0.954)	-266,000 (NW quadrant)	53%	16%	23%
Baseline to 12 months	Decompression vs. no treatment	1,691 (1216 to 2167; p<0.001)	0.080 (0.030 to 0.130; p=0.002)	21138 (NE quadrant)	100%	0%	50%
	Arthroscopy only vs. no treatment	1,391 (901 to 1881; p<0.001)	0.070 (0.020 to 0.119; p=0.008)	19,871 (NE quadrant)	100%	0%	52%
	Decompression vs. arthroscopy only	281 (-142 to 703; p=0.183)	0.006 (-0.045 to 0.056; p=0.819)	46,833 (NE quadrant)	63%	17%	46%
Extrapolation scenario 1	Decompression vs. no treatment	1,691 (1216 to 2167; p<0.001)	0.160 (0.040 to 0.270; p=0.008)	10,569 (NE quadrant)	100%	0%	89%
	Arthroscopy only vs. no treatment	1,391 (901 to 1881; p<0.001)	0.115 (0.009 to 0.221; p=0.035)	12,096 (NE quadrant)	98%	0%	79%
	Decompression vs. arthroscopy only	281 (-142 to 703; p=0.183)	0.032 (-0.072 to 0.136; p=0.528)	8,781 (NE quadrant)	76%	17%	70%
Extrapolation scenario 2	Decompression vs. no treatment	1,940 (1046 to 2834; p<0.001)	0.160 (0.040 to 0.270; p=0.008)	12,125 (NE quadrant)	100%	0%	84%
	Arthroscopy only vs. no treatment	1,575 (799 to 2351; p<0.001)	0.115 (0.009 to 0.221; p=0.035)	13,696 (NE quadrant)	97%	0%	75%
	Decompression vs. arthroscopy only	309 (-484 to 1103; p=0.428)	0.032 (-0.072 to 0.136; p=0.528)	9,656 (NE quadrant),	76%	24%	67%

**Differences are adjusted for baseline Oxford Shoulder Score (costs)/ baseline EQ-5D-3L index (QoL), age at randomisation, gender and randomising site.*
Extrapolation scenario 1: Carry forward QoL from 12 months; assume no differential costs between the treatment arms
Extrapolation scenario 1: Carry forward QoL from 12 months; also carry over cost observed from 6-12 months for each additional six month period
Abbreviations: CI – Confidence interval; NE – North-east quadrant of the cost-effectiveness plane; NW – North-west quadrant of the cost-effectiveness plane; QALY – Quality-adjusted life year; QoL – Quality of life.

Supplementary Table V: Sensitivity analysis to assess the consistency of the incremental cost-effectiveness from baseline to 6 months post randomisation

	Analysis & comparison	Difference in costs (£)* Mean (95% CI; p-value)	Difference in QALYs* Mean (95% CI; p-value)	Mean incremental cost per QALY gained	More effective	Less costly	Cost-effective at £20,000 per QALY gained
Per-protocol population	Decompression vs. no treatment	2,452 (2204 to 2701; p<0.001)	0.030 (0.010 to 0.050; p=0.005)	81,733 (NE quadrant)	100%	0%	0%
	Arthroscopy only vs. no treatment	2,020 (1741 to 2299; p<0.001)	0.031 (0.007 to 0.055; p=0.014)	65,161 (NE quadrant)	100%	0%	0%
	Decompression vs. arthroscopy only	440 (88 to 792; p=0.016)	-0.001 (-0.022 to 0.020; p=0.916)	-440,000 (NW quadrant)	47%	13%	8%
Complete cases population	Decompression vs. no treatment	1,771 (1328 to 2213; p<0.001	0.050 (0.020 to 0.080; p=0.003)	35,420 (NE quadrant)	100%	0%	0%
	Arthroscopy only vs. no treatment	1,298 (819 to 1777; p<0.001)	0.038 (0.008 to 0.068; p=0.014)	34,158 (NE quadrant)	100%	0%	5%
	Decompression vs. arthroscopy only	472 (49 to 895; p=0.030)	0.009 (-0.023 to 0.042; p=0.558)	52,444 (NE quadrant)	30%	7%	7%
0% price discount	Decompression vs. no treatment	1,620 (1217 to 2023; p<0.001)	0.030 (0.010 to 0.050; p=0.007)	54,000 (NE quadrant)	100%	0%	0%
	Arthroscopy only vs. no treatment	1,316 (900 to 1732; p<0.001)	0.029 (0.006 to 0.052; p=0.018)	45,379 (NE quadrant)	100%	0%	3%
	Decompression vs. arthroscopy only	302 (-104 to 708; p=0.138)	-0.001 (-0.022 to 0.020; p=0.954)	-302,000 (NW quadrant)	53%	14%	19%
30% price discount	Decompression vs. no treatment	1,505 (1122 to 1888; p<0.001)	0.030 (0.010 to 0.050; p=0.007)	50,166 (NE quadrant)	100%	0%	0%
	Arthroscopy only vs. no treatment	1,274 (878 to 1671; p<0.001)	0.029 (0.006 to 0.052; p=0.018)	43,931 (NE quadrant)	100%	0%	3%
	Decompression vs. arthroscopy only	229 (-166 to 625; p=0.244)	-0.001 (-0.022 to 0.020; p=0.954)	-229,000 (NW quadrant)	53%	18%	26%

**Differences are adjusted for baseline Oxford Shoulder Score (costs)/ baseline EQ-5D-3L index (QoL), age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*

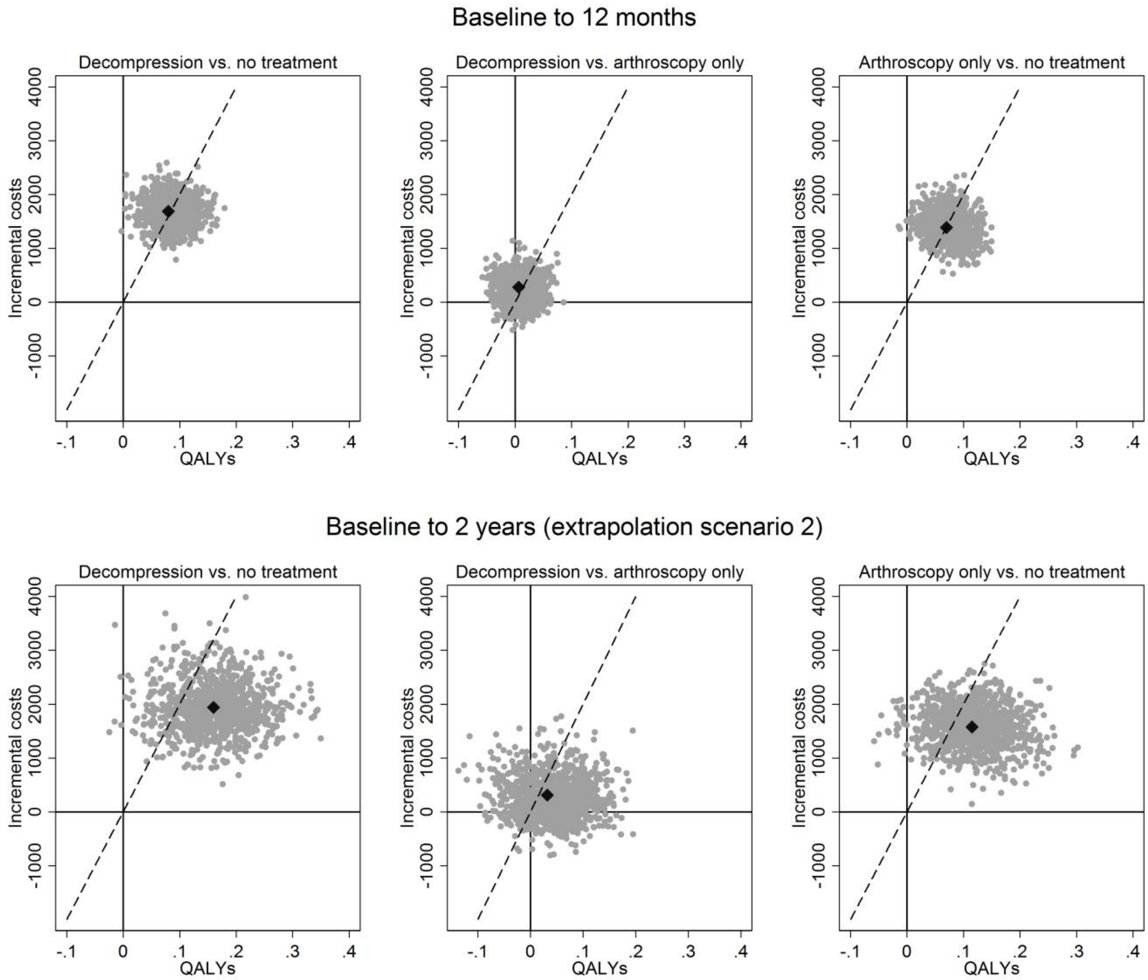
Numbers included in the PP population: decompression, n= 80; arthroscopy only, n=68; no treatment, n=78.
Numbers included in CC population: decompression, n= 81; arthroscopy only, n=86; no treatment, n=79.
Abbreviations: CI – Confidence interval; NE – North-east quadrant of the cost-effectiveness plane; NW – North-west quadrant of the cost-effectiveness plane; QALY – Quality-adjusted life year.

Supplementary Table VI: Sensitivity analysis to assess the consistency of the incremental cost-effectiveness from baseline to 12 months post randomisation

	Analysis & comparison	Difference in costs (£)* Mean (95% CI; p-value)	Difference in QALYs* Mean (95% CI; p-value)	Mean incremental cost per QALY gained	More effective	Less costly	Cost-effective at £20,000 per QALY gained
Per-protocol population	Decompression vs. no treatment	2,567 (2152 to 2982; p<0.001)	0.090 (0.040 to 0.140; p=0.001)	28,522 (NE quadrant)	100%	0%	12%
	Arthroscopy only vs. no treatment	2,220 (1908 to 2532; p<0.001)	0.073 (0.018 to 0.128; p=0.011)	30,410 (NE quadrant)	99%	0%	14%
	Decompression vs. arthroscopy only	346 (-50 to 743; p=0.084)	0.014 (-0.041 to 0.068; p=0.613)	24,714 (NE quadrant)	70%%	6%	49%
Complete cases population	Decompression vs. no treatment	1,741 (1198 to 2283; p<0.001)	0.080 (0.030 to 0.130; p=0.003)	21,763 (NE quadrant)	100%	0%	44%
	Arthroscopy only vs. no treatment	1,325 (754 to 1896; p<0.001)	0.069 (0.023 to 0.115; p=0.005)	19,203 (NE quadrant)	100%	0%	52%
	Decompression vs. arthroscopy only	413 (6 to 820; p=0.047)	0.005 (-0.044 to 0.055; p=0.832)	82,600 (NE quadrant)	58%	9%	31%
0% price discount	Decompression vs. no treatment	1,749 (1265 to 2232; p<0.001)	0.080 (0.030 to 0.130; p=0.002)	21,863 (NE quadrant)	100%	0%	46%
	Arthroscopy only vs. no treatment	1,412 (911 to 1912; p<0.001)	0.070 (0.020 to 0.119; p=0.008)	20,171 (NE quadrant)	100%	0%	51%
	Decompression vs. arthroscopy only	317 (-109 to 743; p=0.137)	0.006 (-0.045 to 0.056; p=0.819)	52,833 (NE quadrant)	63%	14%	44%
30% price discount	Decompression vs. no treatment	1,634 (1166 to 2102; p<0.001)	0.080 (0.030 to 0.130; p=0.002)	20,425 (NE quadrant)	100%	0%	54%
	Arthroscopy only vs. no treatment	1,370 (890 to 1850; p<0.001)	0.070 (0.020 to 0.119; p=0.008)	19,571 (NE quadrant)	100%	0%	52%
	Decompression vs. arthroscopy only	244 (-175 to 663; p=0.240)	0.006 (-0.045 to 0.056; p=0.819)	40,667 (NE quadrant)	63%	20%	49%

**Differences are adjusted for baseline Oxford Shoulder Score (costs)/ baseline EQ-5D-3L index (QoL), age at randomisation, gender and randomising site (i.e. adjusted for clustering within trial site using the 'cluster' option within Stata's regression command).*

Numbers included in the PP population: decompression, n= 80; arthroscopy only, n=68; no treatment, n=78.
Numbers included in CC population: decompression, n= 81; arthroscopy only, n=86; no treatment, n=79.
Abbreviations: CI – Confidence interval; NE – North-east quadrant of the cost-effectiveness plane; NW – North-west quadrant of the cost-effectiveness plane; QALY – Quality-adjusted life year.



Supplementary Figure a: Cost-effectiveness planes.

Note: Points that fall below the dashed line are cost-effective at a £20,000 per QALY willingness-to-pay threshold. Extrapolation scenario 2: Carry forward QoL from 12 months; also carry over cost observed from 6-12 months for each additional six month period

Abbreviations: QALY – Quality adjusted life year

Supplementary Table VII: Employment information over the trial follow-up

	Decompression n (%)	**Arthroscopy only** n (%)	**No treatment** n (%)
Baseline	N=106	N=103	N=104
Yes; full time	50 (41%)	48 (47%)	49 (47%)
Yes; part time	15 (14%)	20 (19%)	12 (12%)
No	41 (39%)	35 (34%)	43 (41%)
6 months	N=87	N=93	N=88
Yes; full time	41 (47%)	40 (43%)	39 (44%)
Yes; part time	15 (17%)	20 (22%)	9 (10%)
No	31 (36%)	33 (35%)	40 (45%)
12 months	N=84	N=87	N=80
Yes; full time	39 (46%)	35 (40%)	35 (44%)
Yes; part time	15 (18%)	23 (26%)	8 (10%)
No	30 (36%)	29 (33%)	37 (46%)

Note: Participants were asked the question: "Are you in paid employment?"
The data presented are based on available data; information was not available for all randomised participants.
There was no evidence of a statistically significant difference (5% significance level) in the proportion of participants in employment (either part-time or full time) at the end of the study between the treatment arms.

Supplementary table VIII: Change in employment due to shoulder problems over the trial follow-up

	Decompression n (%)	**Arthroscopy only n (%)**	**No treatment n (%)**
6 months prior to baseline	N=92	N=92	N=83
Yes; changed hours	7 (8%)	8 (9%)	8 (10%)
Yes; changed job	8 (9%)	9 (10%)	7 (8%)
Yes; stopped working	10 (11%)	4 (4%)	6 (7%)
No	67 (73%)	71 (77%)	62 (75%)
Baseline to 6 months	N=75	N=81	N=75
Yes; changed hours	8 (11%)	9 (11%)	7 (9%)
Yes; changed job	13 (17%)	4 (5%)	6 (8%)
Yes; stopped working	6 (8%)	8 (10%)	5 (7%)
No	48 (64%)	60 (74%)	57 (76%)
6 to 12 months	N=72	N=77	N=68
Yes; changed hours	4 (6%)	2 (3%)	3 (4%)
Yes; changed job	6 (8%)	3 (4%)	7 (10%)
Yes; stopped working	1 (1%)	2 (3%)	3 (4%)
No	61 (85%)	70 (91%)	55 (81%)

Note: Participants were asked the question: "Have you altered your employment in any way over the last six months as a result of shoulder problems?"
The data presented are based on available data; information was not available for all randomised participants.
There was no evidence of a statistically significant difference (5% significance level) in the proportion of participants who changed their employment during the follow-up between the treatment arms.

Supplementary table IX. Number of sick days reported over the trial follow-up

		Decompression Mean (SD) , N	**Arthroscopy only** Mean (SD), N	**No treatment** Mean (SD) , N
6 months prior to baseline	**Total sick days**	10.0 (30.9), N=85	8.0 (24.4), N=84	10.8 (32.2), N=77
	shoulder related sick days	4.7 (21.3), N=84	4.9 (22.5), N=82	6.2 (23.8), N=77
Baseline to 6 months	**Total sick days**	16.0 (24.7), N=69	19.5 (38.6), N=78	9.1 (25.0), N=64
	shoulder related sick days	16.7 (25.3), N=71	16.4 (31.8), N=79	7.3 (24.9), N=64
6 to 12 months	**Total sick days**	11.8 (39.0), N=66	11.3 (36.5), N=75	7.7 (526.6), N=60
	shoulder related sick days	9.9 (34.6), N=63	7.7 (30.8), N=72	6.4 (26.5), N=58
Baseline to 12 months	**Total sick days**	29.1 (55.3), N=59	29.4 (66.7), N=70	15.6 (45.0), N=53
	shoulder related sick days	29.5 (55.2), N=56	25.9 (57.9), N=69	12.3 (46.1), N=51

Note: The data presented are based on available data; information was not available for all randomised participants. There was no evidence of a statistically significant difference (5% significance level) in the number of sick days between the treatment arms.
Abbreviations: SD - standard deviation

Supplementary table X: Use of additional over the counter medication, private practitioners and exercise equipment or activities

		Decompression n/N (%)	**Arthroscopy only** n/N (%)	**No treatment** n/N (%)
Over the counter medication	**6 months prior to baseline**	34/102 (33%)	34/96 (35%)	35/100 (35%)
	Baseline to 6 months	31/82 (38%)	26/87 (30%)	26/84 (31%)
	6 to 12 months	24/77 (31%)	17/88 (19%)	16/74 (22%)
Private practitioner	**6 months prior to baseline**	14/101 (14%)	18/93 (19%)	16/95 (17%)
	Baseline to 6 months	6/82 (7%)	5/87 (6%)	5/83 (6%)
	6 to 12 months	3/77 (4%)	5/86 (6%)	4/74 (5%)
Exercise equipment or activities	**6 months prior to baseline**	9/99 (9%)	12/90 (13%)	4/95 (4%)
	Baseline to 6 months	8/80 (10%)	7/86 (8%)	7/84 (8%)
	6 to 12 months	4/76 (5%)	5/86 (6%)	3/74 (4%)

The data presented are based on available data; information was not available for all randomised participants. There was no evidence of a statistically significant difference (5% significance level) in the use of additional over the counter medication, private practitioners and exercise equipment or activities between the treatment arms.

Supplementary table XI: Out-of-pocket expenses

		Decompression Mean (SD) , N	**Arthroscopy only** Mean (SD) , N	**No treatment** Mean (SD) , N
Over the counter medication	**6 months prior to baseline**	6.9 (14.3), N=102	11.8 (29.5), N=96	9.8 (25.6), N=99
	Baseline to 6 months	6.2 (11.6), N=80	6.4 (16.1), N=86	10.1 (28.2), N=83
	6 to 12 months	5.7 (16.6), N=76	4.0 (12.3), N=88	9.4 (27.0), N=73
	Baseline to 12 months	12.4 (23.3), N=69	11.2 (22.5), N=79	20.5 (46.6), N=69
Private practitioner	**6 months prior to baseline**	29.0 (93.2), N=101	50.6 (139.8), N=93	28.6 (86.2), N=95
	Baseline to 6 months	15.8 (88.3), N=82	6.9 (33.5), N=86	8.8 (49.1), N=83
	6 to 12 months	4.2 (26.6), N=76	12.0 (64.0), N=86	5.7 (25.7), N=74
	Baseline to 12 months	23.1 (102.5), N=70	20.5 (79.2), N=79	10.7 (46.5), N=70
Exercise equipment or activities	**6 months prior to baseline**	8.7 (37.9), N=99	17.7 (61.3), N=90	4.9 (28.0), N=95
	Baseline to 6 months	1.1 (4.2), N=79	8.1 (44.0), N=86	9.9 (46.7), N=84
	6 to 12 months	3.4 (23.2), N=76	4.4 (32.6), N=86	1.1 (10.5), N=74
	Baseline to 12 months	4.5 (24.7), N=68	13.6 (72.9), N=79	13.0 (51.3), N=71

The data presented are based on available data; information was not available for all randomised participants. There was no evidence of a statistically significant difference (5% significance level) in the out-of-pocket expenses between the treatment arms.
Abbreviations: SD - standard deviation