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Abstract

Clinical effectiveness and cost-effectiveness of open and arthroscopic rotator cuff repair [the UK Rotator Cuff Surgery (UKUFF) randomised trial]

Andrew J Carr,[1]* Cushla D Cooper,[1] Marion K Campbell,[2] Jonathan L Rees,[1] Jane Moser,[1] David J Beard,[1] Ray Fitzpatrick,[3] Alastair Gray,[3] Jill Dawson,[3] Jacqueline Murphy,[3] Hanne Bruhn,[2] David Cooper[2] and Craig R Ramsay[2]

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Background: Uncertainty exists regarding the best management of patients with degenerative tears of the rotator cuff.

Objective: To evaluate the clinical effectiveness and cost-effectiveness of arthroscopic and open rotator cuff repair in patients aged ≥ 50 years with degenerative rotator cuff tendon tears.

Design: Two parallel-group randomised controlled trial.

Setting: Nineteen teaching and district general hospitals in the UK.

Participants: Patients ($n = 273$) aged ≥ 50 years with degenerative rotator cuff tendon tears.

Interventions: Arthroscopic surgery and open rotator cuff repair, with surgeons using their usual and preferred method of arthroscopic or open repair. Follow-up was by telephone questionnaire at 2 and 8 weeks after surgery and by postal questionnaire at 8, 12 and 24 months after randomisation.

Main outcome measures: The Oxford Shoulder Score (OSS) at 24 months was the primary outcome measure. Magnetic resonance imaging evaluation of the shoulder was made at 12 months after surgery to assess the integrity of the repair.

Results: The mean OSS improved from 26.3 [standard deviation (SD) 8.2] at baseline to 41.7 (SD 7.9) at 24 months for arthroscopic surgery and from 25.0 (SD 8.0) at baseline to 41.5 (SD 7.9) at 24 months for open surgery. When effect sizes are shown for the intervention, a negative sign indicates that an open procedure is favoured. For the intention-to-treat analysis, there was no statistical difference between the groups, the difference in OSS score at 24 months was –0.76 [95% confidence interval (CI) –2.75 to 1.22; $p = 0.452$] and the CI excluded the predetermined clinically important difference in the OSS of 3 points. There was also no statistical difference when the groups were compared per protocol (difference in OSS score –0.46, 95% CI –5.30 to 4.39; $p = 0.854$). The questionnaire response rate was > 86%. At 8 months, 77% of participants reported that shoulder problems were much or slightly better, and at 24 months this increased to 85%. There were no significant differences in mean cost between the arthroscopic group and the open repair group for any of the component resource-use categories, nor for the total follow-up costs

at 24 months. The overall treatment cost at 2 years was £2567 (SD £176) for arthroscopic surgery and £2699 (SD £149) for open surgery, according to intention-to-treat analysis. For the per-protocol analysis there was a significant difference in total initial procedure-related costs between the arthroscopic group and the open repair group, with arthroscopic repair being more costly by £371 (95% CI £135 to £607). Total quality-adjusted life-years accrued at 24 months averaged 1.34 (SD 0.05) in the arthroscopic repair group and 1.35 (SD 0.05) in the open repair group, a non-significant difference of 0.01 (95% CI –0.11 to 0.10). The rate of re-tear was not significantly different across the randomised groups (46.4% and 38.6% for arthroscopic and open surgery, respectively). The participants with tears that were impossible to repair had the lowest OSSs, the participants with re-tears had slightly higher OSSs and the participants with healed repairs had the most improved OSSs. These findings were the same when analysed per protocol.

Conclusion: In patients aged > 50 years with a degenerative rotator cuff tear there is no difference in clinical effectiveness or cost-effectiveness between open repair and arthroscopic repair at 2 years for the primary outcome (OSS) and all other prespecified secondary outcomes. Future work should explore new methods to improve tendon healing and reduce the high rate of re-tears observed in this trial.

Trial registration: Current Controlled Trials ISRCTN97804283.

Funding: This project was funded by the National Institute for Health Research Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 19, No. 80. See the NIHR Journals Library website for further project information.

Contents

List of tables

List of figures

List of abbreviations

ASES	American Shoulder and Elbow Surgeons
BESS	British Elbow & Shoulder Society
CD	compact disc
CI	confidence interval
CSAW	Can Shoulder Arthroscopy Work
DASH	Disabilities of the Arm, Shoulder and Hand
DMC	Data Monitoring Committee
EQ-5D	European Quality of Life-5 Dimensions
EQ-5D-3L	European Quality of Life-5 Dimensions three levels
GP	general practitioner
HTA	Health Technology Assessment
ICC	intracluster correlation
ICER	incremental cost-effectiveness ratio
IQR	interquartile range
ITT	intention to treat
MHI-5	Mental Health Inventory 5
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NSAID	non-steroidal anti-inflammatory drug
OSS	Oxford Shoulder Score
PROM	patient-reported outcome measure
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SAD	subacromial decompression
SD	standard deviation
SPADI	Shoulder Pain and Disability Index
TSC	Trial Steering Committee
UKUFF	UK Rotator Cuff Surgery
VAS	visual analogue scale

Plain English summary

The rotator cuff is a group of muscles and tendons that control shoulder movement. Degenerative tears of the tendons are a common cause of shoulder pain and dysfunction and some patients may be offered surgery to repair the tear if non-surgical treatment has been unsuccessful.

The UK Rotator Cuff Surgery (UKUFF) trial was designed with patient involvement to assess the best surgical technique for repairing rotator cuff tears. Two different surgical approaches are currently used: open surgery, in which the tendons are reattached to bone under direct vision through a normal surgical incision, and arthroscopic surgery, in which small incisions allow thin metal tubes containing surgical cameras and instruments to be used to carry out the repair. It is unclear which technique produces the best and most cost-effective outcome for patients.

Patients were asked to participate in the study in 47 different hospitals around the UK and were assigned to have either open surgery or arthroscopic surgery.

Patients involved in the study were followed up with telephone and postal questionnaires asking if their symptoms had changed after surgery for 2 years and with a magnetic resonance imaging scan at 1 year to see if the repair had been successful.

Generally, patients in the study benefited from a significant improvement in their symptoms and the rate of complications was very low, even though 40% of the repairs had not healed.

The results of the study show that both open and arthroscopic types of surgery are equally effective and cost-effective in treating shoulder pain and function in patients with rotator cuff tear.

Scientific summary

Background

Painful shoulders are a significant socioeconomic burden; disability of the shoulder can result in time off work and impair the ability to work or perform household tasks. Shoulder problems account for 2.4% of all general practitioner (GP) consultations in the UK and 4.5 million visits to physicians annually in the USA. More than 300,000 surgical repairs for rotator cuff pathologies are performed annually in the USA, where the annual financial burden of shoulder pain management has been estimated to be US$3B. The most frequent indications for surgery are persistent and severe pain combined with functional restrictions that are resistant to conservative treatment. Open surgery involves the rotator cuff being repaired under direct vision through an incision in the skin. Arthroscopic surgery involves the repair being performed through smaller arthroscopic portals with a camera used to visualise the operative site on a monitor. There is conflicting evidence regarding the effectiveness of open and arthroscopic repair. It has been suggested that arthroscopic rotator cuff surgery may have advantages over standard open techniques by causing less trauma to the deltoid muscle and overlying soft tissue. Arguably, this causes less postoperative patient discomfort and allows an earlier return of movement. However, the success of the repair depends partly on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open surgery. Other potential disadvantages of the arthroscopic approach include longer time in the operating room and greater use of costly equipment.

Objective

To determine the effectiveness and cost-effectiveness of open compared with arthroscopic rotator cuff repair.

Methods

Eligible patients were those for whom care had been provided by a participating surgeon, who were deemed suitable for rotator cuff repair surgery and for whom the surgeon was uncertain which surgical procedure was better. In addition, patients had to be aged $\geq$ 50 years, have symptoms from a degenerative full-thickness rotator cuff tear and be able to give informed consent. Surgery was either arthroscopic (fixation of tendon to bone using only arthroscopic techniques) or open (fixation to bone under direct vision through a surgically created opening in the deltoid muscle). The precise technique and method of fixation were not prescribed and surgeons used their preferred and usual technique. The primary outcome measure was the Oxford Shoulder Score (OSS), completed at 24 months after randomisation. The primary measure of cost-effectiveness was the incremental cost per quality-adjusted life-year (QALY). The secondary outcome measures were used to assess functional outcome and patient health-related quality of life. These assessed a range of symptoms often experienced with rotator cuff tears, for example pain, weakness and a loss of function. The measures used included the Shoulder Pain and Disability Index (SPADI), the Mental Health Inventory 5 (MHI-5), the European Quality of Life-5 Dimensions (EQ-5D), participants' ratings of how pleased they were with shoulder symptoms at 12 and 24 months after randomisation, patients' views of the overall state of their shoulder at 8, 12 and 24 months after randomisation and intraoperative and postoperative surgical complications at 2 and 8 weeks post surgery and 12 and 24 months after randomisation. All patients who underwent a rotator cuff repair were assessed with magnetic resonance imaging (MRI) or high-definition ultrasound imaging at 12 months after surgery by an experienced clinician blinded to the treatment group. The sample size was designed to detect a difference in OSS score of 0.38 of a standard deviation (SD) for the comparison of arthroscopic surgery with open surgery. Initially, a conservative comparator (rest then exercise) was included, but because of high rates of crossover to surgery

(77%) this arm was closed down and the trial was reconfigured to a randomised comparison of open and arthroscopic repair. An additional 173 patients from 28 further centres formed surgeon preference groups (91 arthroscopic repair and 82 open repair) and were followed up in the same way.

Results

Nineteen centres throughout the UK recruited to the randomised open surgery and randomised arthroscopic surgery comparison and a further 28 centres recruited to the preference groups where surgeons performed either only open repair or only arthroscopic repair. Recruitment to the trial began on 9 November 2007 and finished on 28 February 2012, although not all centres enrolled over the total period because of the staggered introduction of centres (range 6–39 months from the first to the last participant randomised). Tears were small or medium in size (< 3 cm) in about 75% of participants. The average age of the participants was 63 years, 40% were female and 90% were right-handed. The mean time that the participants had had the shoulder problem before surgery was approximately 2.5 years. There were no substantive differences within or between the groups for any of the sociodemographic factors. The mean OSS was 25.7 across the groups. The EQ-5D, MHI-5 and SPADI measures were not significantly different across and within the groups.

Only around 9% of the participants had received no previous treatment to their shoulder. Previous treatments primarily included physiotherapy and/or cortisone injections. The high frequency of previous conservative treatment probably explains the difficulty in achieving a comparison of a further programme of conservative care, the rest-then-exercise programme, in the context of a pragmatic trial in 47 centres during routine NHS care.

Of the 137 participants randomised to receive open surgical management, 85 (62.0%) underwent an open repair of a tear and five (3.6%) an arthroscopic repair. Of the 136 patients randomised to receive arthroscopic surgical management, 100 (73.5%) received arthroscopic surgery but only 63 (46.3%) received an arthroscopic repair; nine (6.6%) began as an arthroscopic procedure and converted to open surgery. The size of tear and surgical completeness were similar between the randomised groups. The ease of repair, although broadly similar, was reported to be easier in the open procedure (18% of arthroscopic repairs were determined by the surgeon to be easy to perform vs. 36% of the open repairs). Only 162 of 273 (59%) patients randomised to surgery underwent cuff repair. In total, 59 of 273 (22%) withdrew while on the waiting list, with the most common reasons for this being improvement in symptoms and the development of other medical conditions, and 52 of 273 (19%) underwent subacromial decompression and no cuff repair, with the most common reasons for this being that no tear was found or that the tear was impossible to repair.

The mean operation time in minutes was statistically significantly lower in the open procedure group [–12.2, 95% confidence interval (CI) –21.4 to –3.0; $p = 0.010$], as was mean total time in theatre in munites (–12.7, 95% CI –23.5 to –1.9; $p = 0.021$). The number of intraoperative adverse events was generally low. There were 11 (8.1%) participants with any intraoperative complication in the randomised arthroscopic group compared with nine (6.6%) in the open group. The difference was not statistically significant (difference 3.1%, 95% CI –4.8% to 11.0%; $p = 0.190$). Post operation, three participants in the arthroscopic group and three in the open group required inpatient hospitalisation as a result of taking part in the trial. The inpatient admissions were as a result of two participants in each group requiring revision surgery and a single participant in each group having a postoperative complication. One complication was a deep infection requiring formal debridement and vacuum pump application. The patient had this surgery after 3 weeks of treatment by his GP with antibiotics. The other complication involved a participant requiring a longer stay in hospital for a continuous interscalene block in the shoulder for postoperative pain relief and some bleeding during surgery. All complications and revision surgeries were managed within 17 months of randomisation. There were no deaths related to the surgery.

At 2 weeks post surgery very few participants reported being pain free and approximately two-thirds were taking painkillers. Of those participants who were employed, about 80% were still off sick. At 8 weeks the results were similar, with the exception that those who reported no or mild pain increased from 35% to 50%, with an apparent concomitant effect of reducing painkiller use from 66% to 55% and increasing the number of participants returning to usual work (none or a little interference) from 28% to 55%. There were no clinically important differences between or within the groups at either 2 or 8 weeks.

Outcomes at 8, 12 and 24 months were primarily obtained from questionnaire returns. The return rates were similar across groups and ranged from 90% at 8 and 12 months to 86% at 24 months. The OSS increased markedly from baseline (mean 25.7) to 8 months (mean 36.5) and continued to increase thereafter (at a much slower rate) to 24 months (mean 41.5). The groups followed a similar pattern with regard to the EQ-5D, SPADI and MHI-5. At 8 months, 77% of participants reported that shoulder problems were much or slightly better, and this increased to 85% at 24 months. When asked how pleased the participants were with their shoulder symptoms, 77% on average were very or fairly pleased at 8 months, and this increased to 83% by 24 months. Again, the groups responded in a similar manner.

The mean OSS improved from 26.3 (SD 8.2) at baseline to 41.7 (SD 7.9) at 24 months for arthroscopic surgery and from 25.0 (SD 8.0) at baseline to 41.5 (SD 7.9) at 24 months for open surgery for the intention-to-treat (ITT) analysis. There was no statistically significant difference between the groups. When effect sizes are shown for the intervention, a negative sign indicates that an open procedure is favoured. For the ITT analysis there was no statistical difference between the groups, the difference in OSS score at 24 months was –0.76 (95% CI –2.75 to 1.22; $p = 0.452$) and the CI excluded the predetermined clinically important difference in the OSS of 3 points. There was also no statistically significant difference when the groups were compared per protocol (difference in OSS score –0.46, 95% CI –5.30 to 4.39; $p = 0.854$). The rate of re-tear was 46.4% in the arthroscopy group and 38.6% in the open group ($p = 0.256$). In the non-randomised groups the rates were 36.6% for arthroscopic repair and 35.0% for open repair. These differences were not significant. A healed repair (a participant having no tear on the MRI assessment at 12 months) resulted in the greatest improvement in the OSS. In the randomised group the OSS improved from 26.3 (SD 8.2) at baseline to 44.5 (SD 4.1) for the arthroscopic group and from 25.0 (SD 8.0) to 43.6 (SD 5.8) for the open group. The next best results for OSS were for the repaired tears that re-tore, which improved to 41.8 (SD 8.8) in the arthroscopic group and 40.8 (SD 7.6) in the open group. The worst OSS results were seen for the tears that were impossible to repair, which improved to 37.3 (SD 6.1) in the arthroscopic group and 33.8 (SD 9.5) in the open group. The results were similar for the non-randomised groups.

Recognising that caution must be used when interpreting the per-protocol group, we nevertheless note that the lack of important differences between the arthroscopic and the open ITT groups was also observed in the per-protocol data.

Economic evaluation

For the base-case ITT analysis (without adjustment for covariates) there were no significant differences in mean costs between the arthroscopic repair group and the open repair group for any of the component resource-use categories, nor for the total follow-up costs at 12 months or 24 months. The total cost of surgery alone (excluding nights in hospital) was significantly different between the two groups, at £463 (95% CI £260 to £660) more costly for arthroscopic repair. Total QALYs accrued at 2 years averaged 1.34 (SD 0.04) in the arthroscopic repair group and 1.35 (SD 0.04) in the open repair group. The overall treatment cost at 2 years was £2567 (SD £176) for arthroscopic surgery and £2699 (SD £149) for open surgery by ITT analysis. Neither the difference in costs nor the difference in quality-of-life outcomes were statistically significant between the arthroscopic repair group and the open repair group.

Overall, arthroscopic repair was less costly but less effective than open repair in the base-case analysis, resulting in a point estimate for the incremental cost-effectiveness ratio of £30,001 per QALY gained. The probability of arthroscopic repair being less costly than open repair was 75%, and the probability of it being more effective than open repair was 45%.

Comparison with similar randomised trials

The trial was considered in relation to the only other randomised clinical trial of open compared with arthroscopic rotator cuff repair published in 2013. This was a single-centre study of 100 patients with small and medium tears with unblinded follow-up to 1 year using the Disabilities of the Arm, Shoulder and Hand score. This trial also reported no difference in outcome between the groups. It did not include a health economic analysis.

Conclusions

In patients aged ≥ 50 years with a degenerative rotator cuff tear there was no difference in effectiveness or cost-effectiveness between open and arthroscopic repair at 2 years for the primary outcome (OSS) and all other prespecified secondary outcomes. Rotator cuff surgery resulted in marked improvement in symptoms (OSS 25.7/48 at baseline to 41.5/48 at 2 years). A healed repair gave the best outcome, followed by a repair that subsequently re-tore. The worst outcome was in patients whose tear was unrepairable at surgery. Re-tears were found in 93 of 233 (40%) patients who underwent repair surgery, with no difference between the open group and the arthroscopic group. Re-tears occurred after repairs to all tear sizes and the risk of re-tear was not influenced by age.

Implications for health care

Rotator cuff surgery results in a significant improvement in symptoms in patients who have completed a programme of conservative care with symptom duration of > 12 months and there is no difference in clinical effectiveness or cost-effectiveness between open and arthroscopic rotator cuff repair. There is no evidence of an effect of age or tear size on clinical outcome. The overall re-tear rate was 40%, with no difference between the groups. The statistically significant treatment effect seen in all patients, including those in whom a repair was not possible or in whom there was a postoperative re-tear, suggests that there are other treatment effects. Per protocol the costs of arthroscopic surgery were significantly greater than those of open surgery. This is largely because of the longer operating time.

Recommendations for research

This unique study cohort provides the opportunity to determine the longer-term consequences of rotator cuff tear and repair. There is a case for continuing the follow-up of the patients who underwent surgery and who had a repair that healed, re-tore or was impossible to repair. There is early evidence at 2 years' follow-up that these groups have different outcomes. It is important to know whether these differences remain in the longer term and whether or not particular groups are prone to further deterioration.

There is a need to evaluate cost-effectiveness over a longer period than 24 months, using further follow-up data from this study and elsewhere on the longer-term consequences of rotator cuff tear and repair.

It would be of value to explore the basis of the treatment effect seen with a randomised controlled trial of rotator cuff repair compared with placebo surgery.

Trial registration

This trial is registered as ISRCTN97804283.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

This report describes the results of the UK Rotator Cuff Surgery (UKUFF) trial assessing the clinical effectiveness and cost-effectiveness of arthroscopic compared with open rotator cuff repair for people with full-thickness rotator cuff tears. This comparison was commissioned and funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. The trial began in 2007 and initially also included a non-operative comparator of a rest-then-exercise programme. However, because of high crossover from the rest-then-exercise group to surgery, the trial was reconfigured in 2010 to a comparison of arthroscopic and open repair only.

Rotator cuff tear

The prevalence of shoulder complaints in the UK is estimated to be 14%, with 1–2% of adults consulting their general practitioner (GP) annually regarding new-onset shoulder pain.[1] Rotator cuff pathology, including tendonitis, calcific tendonitis and rotator cuff tears, reportedly accounts for up to 70% of shoulder pain problems.[2] Painful shoulders pose a substantial socioeconomic burden. Disability of the shoulder can impair the ability to work or perform household tasks and can result in time off work.[3,4] Shoulder problems account for 2.4% of all GP consultations in the UK and 4.5 million visits to physicians annually in the USA.[5,6] More than 300,000 surgical repairs for rotator cuff pathologies are performed annually in the USA, where the annual financial burden of shoulder pain management has been estimated to be US$3B.[7]

Rotator cuff pathology is associated with progressive change in the shape of the acromion, with 'spurs' forming at its anteroinferior margin. Some reports suggest that these spurs narrow the subacromial space, thereby making physical contact more likely in certain positions of the arm. This is most notable in abduction and elevation of the arm and is sometimes referred to as 'painful arc' or impingement because pain is maximal in the mid-range of movement. This process is argued to result in inflammation of the rotator cuff tendons (particularly the supraspinatus tendon) and the overlying subacromial bursa. A conflicting theory suggests that such mechanisms are not causative and that intrinsic age-related degeneration of the tendon is the main determinant of inflammation and symptoms.[8,9]

Rotator cuff tear refers to structural failure in one or more of the four muscles and tendons that form the rotator cuff. Any tear that does not extend all the way through the tendon is termed a partial-thickness tear. Asymptomatic full-thickness tears of the rotator cuff are very common in the general population. It is estimated that the overall prevalence of tears is 34% and that risk increases significantly with age.[10] Partial tears are more prevalent than full-thickness tears.[11]

Conservative management

Conservative treatment may include rest, exercise, topical non-steroidal anti-inflammatory drugs (NSAIDs), oral corticosteroids, oral paracetamol, opioid analgesics, physiotherapy, activity modification, acupuncture, platelet-rich plasma injections, extracorporeal shockwave therapy, suprascapular nerve block, laser treatment, autologous blood injections, intra-articular NSAID injections, subacromial corticosteroid injections, electrical stimulation, ice and ultrasound.

A search of MEDLINE, EMBASE and The Cochrane Library up to August 2009 for treatment of shoulder pain was undertaken.[12] Harm alerts from relevant organisations, such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), were included. The review found 71 systematic reviews, randomised controlled trials (RCTs) or observational studies that met the inclusion criteria. Grading of Recommendations Assessment, Development and Evaluation (GRADE) of the quality of evidence for interventions was performed.[2] It is not known whether topical NSAIDs, oral corticosteroids, oral paracetamol or opioid analgesics improve shoulder pain, although oral NSAIDs may be effective in the short term in people with acute tendonitis/subacromial bursitis. If pain control fails, the diagnosis should be reviewed and other interventions considered. Physiotherapy may improve pain and function in people with mixed shoulder disorders compared with placebo. Platelet-rich plasma injections may improve the speed of recovery in terms of pain and function in people having open subacromial decompression for rotator cuff impingement, but further evidence is needed. Acupuncture may not improve pain or function in people with rotator cuff impingement compared with placebo or ultrasound. Extracorporeal shockwave therapy may improve pain in calcific tendonitis. There is some evidence that suprascapular nerve block, laser treatment, arthroscopic subacromial decompression and rotator cuff repair may be effective in some people with shoulder pain. There is no evidence to support the use of autologous blood injections, intra-articular NSAID injections, subacromial corticosteroid injections, electrical stimulation, ice or ultrasound. Concern exists regarding the potential longer-term damaging consequences of corticosteroid injection.[13]

Role of imaging

Imaging is most useful in directing treatment in secondary care if conservative care has failed. A large proportion of the general population will demonstrate abnormalities on imaging of the rotator cuff.[14] Imaging findings need to be interpreted in the context of symptoms, disability and response to treatment. A high proportion of patients with rotator cuff pain will respond to conservative treatment.[15] The only reliable non-interventional method of determining if a rotator cuff tear has healed is use of postoperative imaging, either magnetic resonance imaging (MRI) or ultrasonography.

Surgical management

The most frequent indications for surgery are persistent and severe pain combined with functional restrictions that are resistant to conservative measures. Symptoms of pain and weakness typically disrupt daily activities and night pain affects sleep. Symptoms of a minimum of 3 months' duration that are sufficiently severe to disrupt daily activities and rest or sleep and failure of standard conservative care (analgesics, rest and physiotherapy and cortisone injection) are usually required before surgery is considered. Surgical repair may be advised in cases of full-thickness rotator cuff tear with persistent pain and weakness after conservative treatment. A rotator cuff repair operation aims to reattach the torn tendons to the humeral bone. In general, two approaches are available for surgical repair. Open surgery involves the rotator cuff being repaired under direct vision through an incision in the skin. Arthroscopic surgery is keyhole surgery and involves the repair being performed through arthroscopic portals into the shoulder. A subacromial decompression (SAD) or acromioplasty to create space around the repaired tendon is usually performed in association with the tendon repair. Reports of the outcome of such surgery are conflicting and evidence for effectiveness is unclear.[16–18] An assessment of the treatment cost of impingement suggests that the addition of surgery, in comparison with exercise treatment alone, is not cost-effective.[19]

Comparative studies of subacromial decompression and non-operative treatment options such as physiotherapy have not shown any significant difference in outcome between the two treatment modalities.[20–23] A growing number of studies have tried to assess the effectiveness of subacromial decompression against a control. Three studies of patients undergoing rotator cuff repair, including or excluding subacromial decompression in their operative treatment, did not demonstrate any difference in outcome between the groups.[24–26] A RCT of subacromial decompression plus subacromial bursectomy compared with bursectomy alone reported no significant difference in clinical outcome between the two groups. This finding suggests that removing acromial spurs might not be necessary.[27]

The management of partial tears is particularly controversial and patients with such tears have commonly been treated conservatively. Favourable results have been reported following debridement of partial tears in association with subacromial decompression.[28] Higher rates of re-rupture are associated with repairs of larger tears, increased patient age and increased fatty degeneration of the cuff muscles.[29–32] Partial tears are most commonly managed without repair, but some authors advocate repair to prevent progression to full-thickness tears. The evidence supporting this approach is weak.[11] There is also uncertainty regarding the relative value of conservative care, repair surgery and debridement surgery for large and massive tears.[33–36] High failure rates of 13–68% have been reported for surgical repair of rotator cuff tears, irrespective of the surgical technique employed.[37–39] Some studies have suggested that re-rupture rates are associated with poorer outcomes.[40] Surgical decision-making in the management of rotator cuff tears was reviewed by Dunn *et al.*[41] They surveyed surgeons in the USA and found considerable variation in decision-making. This included the type of surgery, the surgical techniques employed and the type and duration of conservative treatment, including cortisone injections, physiotherapy, rest, analgesia and home exercises. Rates of medical visits for rotator cuff pathology in the USA were reviewed between 1996 and 2006. The volume of rotator cuff repairs had increased by 141% and the unadjusted number of arthroscopic repairs increased by 600% compared with a 34% increase in open repairs.[42] The volume of arthroscopic subacromial decompressions has also increased significantly over time. Recent figures from the USA report a 240% increase (from 30.0 to 101.9 per 100,000 people per year) in use of the procedure in New York state between 1996 and 2006.[43] This compares to a 78.3% increase in ambulatory orthopaedic surgery overall. Similar increases have recently been reported in the UK.[44] The introduction of less invasive arthroscopic techniques accounts for some of the overall increased rate of surgery, but does not explain regional variation. Patient and disease characteristics have not changed over time and there is a growing concern that this procedure is being overused. Observational studies of subacromial decompression surgery show positive results in terms of pain reduction and functional outcome, with high patient satisfaction rates. However, equally good outcomes have been noted in two studies following patients who had arthroscopic rotator cuff debridement or open rotator cuff repair in the absence of a subacromial decompression.

Rationale for the study design

The objective of the original commissioned call was to conduct a pragmatic multicentre randomised clinical trial to obtain good-quality evidence of the effectiveness and cost-effectiveness of conservative care compared with arthroscopic surgical repair compared with open surgical repair for the treatment of degenerative rotator cuff tears. Because of high crossover from the conservative arm to surgery the study was reconfigured to a comparison of the two surgical techniques only. There is conflicting evidence regarding the effectiveness of open and arthroscopic repair.[12,45–47] Proponents of arthroscopic rotator cuff surgery suggest that the procedure may have advantages over standard open techniques by causing less trauma to the deltoid muscle and overlying soft tissue. Arguably, this causes less postoperative patient discomfort together with earlier return of movement. However, the success of the repair depends partly on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open/mini-open surgery. Other potential disadvantages of the arthroscopic approach include increased technical difficulty and longer time in theatre. There is a need to compare the outcomes of the two surgical techniques.

Literature update since the call

A review updating the literature published since the original commissioned call was undertaken to inform this report and set the results in context. Only reports of RCTs were included. Quasi-RCTs, which use methods of allocating participants to a treatment that are not strictly random, for example date of birth, hospital record number or alternation, were excluded.

Types of participants

Randomised controlled trials of adults aged ≥ 18 years with a degenerative rotator cuff tear as reported in the primary studies (e.g. confirmed by physical examination, MRI, ultrasound or MRI arthrogram) were included. RCTs of adults undergoing surgery for other types of rotator cuff disease, shoulder instability, joint replacement or fractures were excluded.

Types of interventions

All randomised comparisons between a surgical procedure (e.g. open or arthroscopic) and another surgical procedure for treating rotator cuff tear were included. Randomised comparisons between a surgical procedure and a non-surgical procedure (e.g. physiotherapy, drug therapy) were also included. RCTs in which the primary aim was to compare different types of surgical technique (e.g. different suturing techniques) as part of the surgical repair of the rotator cuff were excluded.

Types of outcome measures

The primary outcome for each RCT and time point when measured, as reported by the authors, was recorded. When reported by the authors, the primary outcome was that used for the calculation of the sample size. Primary outcomes included pain, disability or function measured using shoulder-specific instruments such as the Constant score,[48] American Shoulder and Elbow Surgeons (ASES) Shoulder Score[49] or the Disabilities of the Arm, Shoulder and Hand (DASH) score.[50]

Search methods for identification of studies

We searched Ovid MEDLINE from 2006 to March 2014 for possible reports of RCTs. The search strategy used was based on one developed by Coghlan *et al.*[16] for a Cochrane review of surgery for rotator cuff disease. This search strategy was modified to account for changes to the medical subject heading (MeSH) terms since the original search was conducted in 2006, the addition of free-text terms and the replacement of the original RCT filter used with the Cochrane sensitivity- and precision-maximising version RCT filter [2008 version; see http://handbook.cochrane.org/chapter_6/box_6_4_b_cochrane_hsss_2008_sensprec_pubmed.htm (accessed 23 August 2015)] (see *Appendix 4* for search strategy). We also searched the World Health Organization (WHO) International Clinical Trials Registry Platform[51] to identify reports of any ongoing RCTs. One author screened the titles and abstracts of all retrieved records. Full articles were then obtained for any potentially eligible studies and assessed using the predefined eligibly criteria described earlier.

Results

Description of studies

The search strategy identified 477 potentially eligible studies. Of these, eligible studies were identified as those comparing a surgical intervention with another surgical intervention and those comparing a surgical intervention with a non-surgical intervention.

Surgery compared with surgery

Six RCTs[26,52–56] comparing a surgical intervention with another surgical intervention were identified (*Table 1*). Of these six trials, one RCT[56] is ongoing, with completed recruitment but final results awaiting publication. Two other trials[57,58] were identified comparing two different types of surgical intervention; however, these were excluded as the patients were not randomised.

Of the five completed RCTs,[26,52–55] three were single-centre studies and all were relatively small, ranging from 73 to 114 participants per trial, with a mean participant age between 57 and 60 years. Four RCTs included participants with full-thickness rotator cuff tears[26,52,54,55] and one included participants with small and medium rotator cuff tears.[53] The type of surgical interventions differed between trials, with one RCT comparing arthroscopic repair with mini-open repair,[53] one comparing mini-open repair arthroscopic acromioplasty with open surgical repair[55] and three comparing arthroscopic with acromioplasty repair with arthroscopic without acromioplasty repair.[26,52,54] The choice of primary outcome also varied across studies and included pain, disability or function measured using shoulder-specific instruments. Four[26,52,54,55] of the five completed RCTs reported blinded assessment of these outcomes. Overall, no RCT showed a statistically significant difference between the two types of surgical intervention being compared.

Surgery compared with non-surgery

Three RCTs[59–61] comparing a surgical intervention with a non-surgical intervention were identified, of which one[61] is ongoing, having completed recruitment but with final results awaiting publication (*Table 2*).
Of the two completed RCTs, one[59] was a multicentre study and both were relatively small, ranging from 103 to 173 participants per trial, with a participant age of between 60 and 65 years. One RCT[59] was a three-arm trial comparing open surgical repair, acromioplasty and physiotherapy with acromioplasty and physiotherapy and physiotherapy alone. This trial found no statistically significant difference between the interventions being compared at 1 year based on the Constant shoulder score.[48] The other RCT[60] compared open surgical repair (or mini-open repair) with physiotherapy and found a statistically significant difference in favour of surgery at 1 year based on the Constant shoulder score.[48]

TABLE 1 Randomised controlled trials comparing surgical with alternative surgical interventions for treating rotator cuff tear

Study ID	Study design[a]	Blinding	Sample size	Participants	Intervention	Comparator	Primary outcome[b]	Results
Included studies								
Abrams 2014[52]	RCT, single centre	Outcome assessor blinded	114	Full-thickness rotator cuff tear – mean age 59 years	Arthroscopic with acromioplasty repair	Arthroscopic without acromioplasty repair	ASES score at 2 years	No statistically significant difference
van der Zwaal 2013[53]	RCT, single centre	Not blinded	100	Small to medium rotator cuff tear – mean age 57 years	Arthroscopic repair	Mini-open repair	DASH score at 1 year	No statistically significant difference; mean difference –3.4 (95% CI –10.2 to 3.4)
MacDonald 2011[54]	RCT, multicentre	Subject and outcome assessor blinded	86	Full-thickness rotator cuff tear – mean age 57 years	Arthroscopic repair with acromioplasty	Arthroscopic repair without acromioplasty	Quality of life specific to rotator cuff disease (WORC) at 2 years	No statistically significant difference; mean difference –6.8 (95% CI –15.7 to 2.1)
Mohtadi 2008[55]	RCT, multicentre	Outcome assessor blinded	73	Full-thickness rotator cuff tear – mean age 57 years	Arthroscopic acromioplasty with mini-open repair	Open surgical repair	Rotator cuff quality-of-life score (RC-QOL) at 2 years	No statistically significant difference; $p = 0.943$
Gartsman 2004[26]	RCT, single centre	Outcome assessor blinded	93	Full-thickness supraspinatus tear – mean age 60 years	Arthroscopic with acromioplasty repair	Arthroscopic without acromioplasty repair	ASES score at 1 year	No statistically significant difference; $p = 0.363$
Ongoing study								
MacDermid 2006[56]	RCT, multicentre	Subject and outcome assessor blinded	225	Small (≤ 1 cm) to medium (1–3 cm) rotator cuff tear – age 18–75 years	Arthroscopic repair	Mini-open repair	Quality of life specific to rotator cuff disease (WORC index) within 2 years	
Excluded studies								
Cho 2012[57]	Quasi-RCT, single centre	Not reported	60	Small (< 3 cm) supraspinatus tear – mean age 56 years	Arthroscopic repair	Mini-open repair	Pain score (VAS) at 6 months	No statistically significant difference; $p = 0.98$
Kasten 2011[58]	Quasi-RCT, single centre	Not reported	34	Supraspinatus tear – mean age 60 years	Arthroscopic repair	Mini-open repair	Pain score (VAS) at 3 months	No statistically significant difference

CI, confidence interval; VAS, visual analogue scale; WORC, Western Ontario Rotator Cuff.
a Quasi-RCT refers to study using inadequate method of randomised (e.g. alternation or consecutive recruitment).
b As reported by the authors of the primary study, ideally that used for the sample size calculation.

TABLE 2 Randomised controlled trials comparing surgical with non-surgical interventions for treating rotator cuff tear

Study ID	Study design	Blinding	Sample size	Participants	Intervention	Comparator	Primary outcome[a]	Results
Included studies								
Kukkonen 2014[59]	RCT, multicentre	Outcome assessor blinded	173 (180 shoulders)	Atraumatic symptomatic supraspinatus tendon tear – mean age 65 years	Open surgical repair, acromioplasty and physiotherapy	Acromioplasty and physiotherapy *or* physiotherapy	Constant score at 1 year	No statistically significant difference; $p = 0.34$
Moosmayer 2010[60]	RCT, single centre	Outcome assessor blinded	103	Small (≤ 1 cm) to medium (1–3 cm) rotator cuff tear – mean age 60 years	Open surgical repair ($n = 42$) or mini-open repair ($n = 9$)	Physiotherapy	Constant score at 1 year	Statistically significant difference in favour of surgery; mean difference 13 (95% CI. 4.9 to 21.1)
Ongoing study								
Lambers Heerspink 2011[61]	RCT, multicentre	Not reported	108	Atraumatic rotator cuff tear – age 45–75 years	Open surgical repair with acromioplasty	Physiotherapy, NSAIDs (if indicated), subacromial infiltration with corticosteroids	Constant score at 1 year	

CI, confidence interval.
a As reported by the authors of the primary study, ideally that used for the sample size calculation.

Chapter 2 Methods

At the outset (July 2007) the UKUFF study had two complementary components [UKUFF original Research Ethics Committee (REC) reference number 07/Q1606/49]:

1. a multicentre, pragmatic RCT comparing open and arthroscopic surgical treatments with a non-operative programme of rest then exercise to assess their relative clinical effectiveness
2. an economic evaluation of the treatments to compare the cost-effectiveness of the management streams, identify the most efficient provision of future care and describe the resource impact that various policies for surgical rotator cuff repair would have on the NHS.

Eligible patients who consented to participate in the study were randomly allocated to arthroscopic surgery, open surgery or a programme of rest then exercise. Participants completed patient-reported outcome measures (PROMs) at baseline and then at 8, 12 and 24 months post randomisation. Questionnaires were also completed by telephone at 2 and 8 weeks post treatment. For those patients randomised to surgery, who had a complete repair of the rotator cuff, MRI or an ultrasound scan was also performed 12 months after their surgery.

Randomisation in the original study design was organised within three strata depending on surgeons' stated preparedness to randomise. A detailed survey of the members of the British Elbow & Shoulder Society (BESS) was conducted in preparation for this study. This survey showed that, at the time, only around 15% of surgeons regularly undertook arthroscopic surgery. Of the surgeons who regularly performed arthroscopic surgery, only 8% indicated that they would be prepared to randomise between surgical treatments. The remainder were happy to randomise between arthroscopic surgery and the rest-then-exercise programme. The majority of surgeons indicated that they performed only open surgery. Surgeons who performed only open surgery did not appear to have equipoise for open surgery compared with arthroscopic surgery.

Reflecting this lack of individual uncertainty around certain comparisons, the trial was designed such that surgeons could randomise between:

- stratum A – arthroscopic surgery compared with open surgery compared with rest then exercise
- stratum B – arthroscopic surgery compared with rest then exercise
- stratum C – open surgery compared with rest then exercise.

Reconfigured study design

A high rate of crossover (77%) of the 214 patients in the rest-then-exercise programme to surgery was observed and so the trial was adapted and reconfigured on the instruction of the funder in 2009 after consultation with the Trial Steering Committee (TSC) and the Data Monitoring Committee (DMC). Crossover did not occur at a consistent or predictable time point. The reconfigured design was a two-way parallel-group RCT of open compared with arthroscopic rotator cuff repair (UKUFF reconfigured REC reference number 10/H0402/24, April 2010). At the time of reconfiguration there were 131 participants in stratum A ($n = 43$, arthroscopic surgery; $n = 44$, open surgery; and $n = 44$, rest then exercise), 181 in stratum B ($n = 91$, arthroscopic surgery; and $n = 90$, rest then exercise) and 162 in stratum C ($n = 82$, open surgery; and $n = 80$, rest then exercise). The 87 patients already randomised between arthroscopic and open surgery (stratum A) were carried through to the subsequent reconfigured trial. After the reconfiguration it was calculated that a further 180 patients should be recruited and followed up for 2 years as per the original protocol, leading to a total of 267 patients treated with surgery.

During the period between 2007 and 2010, surgical opinion had changed and an increased number of surgeons were in equipoise between open and arthroscopic surgery. The UKUFF trial was reconfigured as a pragmatic multicentre study involving 20 surgeons from 16 UK centres; 15 of these surgeons had originally recruited to stratum A.

Patient and public involvement and engagement

From the outset patients were involved and engaged in the design of the trial. A patient representative (D Farrar-Hockley) was a member of the group designing the trial. He subsequently became a member of the TSC.

Interventions

Conservative care

For the original study a conservative regime of rest then exercise was developed. In view of the lack of evidence for type or dose of exercise therapy, a consensus approach was adopted with input from five physiotherapists, all with expertise and publications in shoulder physiotherapy. It was anticipated that most patients would have already undergone physiotherapy before referral to a surgeon and therefore further similar treatment would not be appropriate. In addition, there was a need for standardisation across a large geographical area and number of locations over a considerable period of time. It was decided to deliver, by post, a high-quality booklet to patients in their own home with an accompanying compact disc (CD) showing moving images. Information was given regarding rotator cuff tears and general and specific exercise options. The package included a sling, with advice to start with relative shoulder rest, using the sling if necessary, and to then start exercising. A free telephone helpline was available with physiotherapy expertise. However, because of the high crossover rate to surgery (77%), this treatment arm was discontinued in the reconfigured trial.

Surgery and surgeons

Surgery was either arthroscopic (fixation of tendon to bone using only arthroscopic techniques) or open (fixation to bone under direct vision through a surgically created opening in the deltoid muscle). The precise technique and method of fixation were not prescribed and surgeons used their preferred and usual technique. Details of the surgical technique used, including the method of repair and theatre equipment used (e.g. types of anchor), were recorded on a standard form (see *Appendix 5*), as well as the size of the tear, the ease of repair and the completeness of the repair. If circumstances dictated that the allocated surgical technique could not be carried out then any alternative procedure was recorded.

Participating surgeons required a 'minimum level of expertise' for the types of surgery undertaken. Only consultant orthopaedic shoulder surgeons with a minimum of 2 years' experience in consultant practice could participate. Surgeons had to perform a minimum of five cases per year. The participating surgeons represented a cross-section of high-, medium- and low-volume practitioners from both general hospitals and teaching hospitals. Because of the nature of the study's NHS setting, some patients recruited to the UKUFF study had their surgery performed by non-UKUFF surgeons. The trial accepted data from patients who were recruited by a UKUFF surgeon but who went on to have their surgery performed by a colleague of the same or similar experience and position or by a supervised senior trainee. An assessment of the surgeons' position and experience was made by the chief investigator. NIHR local research networks provided help with patient identification, recruitment and obtaining any required data from patient notes. Patient eligibility was confirmed by the local consultant orthopaedic surgeons.

Study population

Eligible patients were those for whom care had been provided by a participating surgeon and who were deemed suitable for rotator cuff repair surgery, with the surgeon uncertain which surgical procedure was better. In addition, patients had to be aged ≥ 50 years, have symptoms from a degenerative full-thickness rotator cuff tear and be able to give informed consent.

Study registration/consent to randomise

Recruitment of patients occurred through a two-step process. A patient's eligibility was assessed by the local consultant orthopaedic surgeon, who introduced the trial to the patient using a prompt sheet and a patient assessment form. If the patient was interested in participating, the surgeon then provided the patient with a copy of the patient information sheet (see *Appendix 6*), which summarised what the study involved and answered any questions the patient might have.

If the patient was willing to enter the trial then an initial consent form was signed, which allowed the patient's details to be forwarded to the central study office in Oxford. The office then issued to the participant, by post, an invitation letter, the comprehensive patient information sheet (see *Appendix 6*), a consent form and a baseline questionnaire (see *Appendix 7*) with a prepaid return envelope. Patients were encouraged to contact the office or their surgeon if they had any further questions or concerns. Patients who had not returned their questionnaire and consent form within a week were telephoned by a member of the study team in Oxford. This contact allowed the patient to ask questions about the study and permitted the team to assess whether the patient was still willing to participate. When the full consent form and baseline questionnaire had been returned to the Oxford office the patient then officially entered the trial and was randomised to one of the surgical options. A copy of the signed consent form was returned to the patient.

Randomisation was by computer allocation using the service provided by the Centre for Healthcare Randomised Trials (CHaRT) at the Health Services Research Unit, University of Aberdeen. Allocation was minimised using surgeon, age and size of tear. After randomisation the participant was considered irrevocably part of the trial for the purpose of the research, irrespective of what occurred subsequently.

Outcomes

The primary outcome measure was the Oxford Shoulder Score (OSS)[62] completed at 24 months after randomisation. The OSS is a 12-item shoulder-specific PROM that was developed, with patients, for the assessment of shoulder pain and function in the context of shoulder surgery, particularly in trials. Items refer to the past 4 weeks and each offers five ordinal response options. Originally, these were scored from 1 to 5 (5 = most severe) and then summed to produce a summary score ranging from 12 to 60. Subsequently, the recommended method of scoring was changed.[63] Under the new system, each item on the OSS is scored from 0 to 4, with 4 representing the best outcome (i.e. the opposite direction from the original method of scoring). When the 12 items are summed, this produces an overall score ranging from 0 to 48, with 48 being the best outcome. The OSS has been demonstrated to be reliable, valid, responsive and very acceptable to patients.

The primary measure of cost-effectiveness was the incremental cost per quality-adjusted life-year (QALY).

The secondary outcome measures were used to further assess functional outcome and patient health-related quality of life. These assessed a range of symptoms often experienced with rotator cuff tears, for example pain, weakness and loss of function. These included:

- Shoulder Pain and Disability Index (SPADI)[64] at 8, 12 and 24 months after randomisation. The SPADI is a self-administered questionnaire, developed by a panel of rheumatologists and a physiotherapist, to measure shoulder pain and disability in an outpatient setting.[64] It contains 13 items that assess two domains: shoulder pain (five items) and disability (eight items), all with reference to the last week. The original version scored each item on a visual analogue scale (VAS). A second version, used in this trial, replaced the VAS with a 0–10 numerical rating scale.[65] Item responses within each subscale are summed and transformed to a score out of 100. A mean is taken of the two subscales to give a total score out of 100, with a higher score indicating greater impairment or disability. The SPADI is reliable, valid and responsive.[64]
- Mental Health Inventory 5 (MHI-5)[66] at 8, 12 and 24 months after randomisation. The MHI-5 is the mental health subscale of the Short Form questionnaire-36 items (SF-36) generic health status measure.[67] It contains five items that address anxiety, depression, loss of behavioural or emotional control and psychological well-being, all with reference to the past 4 weeks. Each item offers responses on a 6-point scale (ranging from 'all of the time' to 'none of the time'). The total score is calculated by reversing the answers to two items (the third and fifth), summing the scores, and transforming the raw scores to a scale ranging from 0 to 100. A higher score indicates better mental health. The MHI-5 has been demonstrated to be good at detecting major depression, affective disorders generally and anxiety disorders.[66]
- European Quality of Life-5 Dimensions three levels (EQ-5D-3L)[65,68] at 8, 12 and 24 months after randomisation. The EQ-5D-3L is a standardised generic instrument for use as a self-completed measure of health outcome. It provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care, as well as population health surveys, and consists of five items on mobility, self-care, pain, usual activities and psychological status, with three possible answers for each item (1 = no problem, 2 = moderate problem, 3 = severe problem). The response for each item/domain is converted to a quality-of-life estimate using an algorithm (see *Chapter 6* for further details) to produce an index score for each patient. Negative scores represent health states worse than death, 0 represents the state of worst health and 1.00 represents full health.
- The OSS[62] completed at 8 and 12 months after randomisation.
- Participants' view of the overall state of their shoulder compared with an earlier time point ('transition item') at 8, 12 and 24 months after randomisation. There were five possible responses to this item: 'much better', 'slightly better', 'no change', 'slightly worse' or 'much worse'.
- Participants' rating of how pleased they were with their shoulder symptoms at 12 and 24 months after randomisation. There were four possible responses to this item: 'very pleased', 'fairly pleased', 'not very pleased' or 'very disappointed'.
- Surgical complications (intra- and postoperative) at 2 and 8 weeks post surgery and at 12 and 24 months after randomisation.
- 12-month postoperative imaging.

Data collection

Outcome assessment was conducted using questionnaires that participants self-completed and, as such, interviewer bias and clinical rater bias were avoided. This form of outcome measurement has consistently performed well compared to clinician-based assessments and general health status measures. All participants, including those who had withdrawn from their allocated intervention but who still wished to be involved in the study, were followed up, with analysis based on the intention-to-treat (ITT) principle.

Participants received questionnaires at the following time points:

- baseline (see *Appendix 7*) – questionnaire completed before randomisation
- 2 and 8 weeks post treatment (see *Appendix 8*) – questionnaire completed by telephone
- 8, 12 and 24 months post randomisation (see *Appendix 9*) – questionnaire completed by post.

The baseline and 12 and 24 months' post-randomisation questionnaires also incorporated a section that measured cost-effectiveness. This included questions relating to primary care consultations, other consultations, out-of-pocket costs and the work impact of the intervention received.

The study team based at the Health Services Research Unit, University of Aberdeen, contacted participants whose questionnaires had not been returned. In the first instance this was through a reminder letter by post or e-mail, depending on participant preference. If a questionnaire had still not been returned within the specified time frame, the study team telephoned the participant and addressed any administrative issues that may have arisen, such as change of address or loss of questionnaire. If any clinical issues were identified, the study team in Oxford contacted participants, if appropriate, and addressed these issues. The time period allocated to the follow-up checks depended on which outcome assessment was involved.

Magnetic resonance imaging and ultrasound scans

Postoperative imaging was performed on patients who had undergone a repair. It was not performed if a repair was either impossible to perform or when no tear was found. Both the MRI and the ultrasound scans were undertaken locally to the participant and were arranged by the study office in Oxford, at a time agreed by the trust and the participant. The scans were collected centrally. The MRI scans were reported by an independent consultant radiologist who was blinded to the type of surgery that was performed. Because of the operator-dependent nature of the ultrasound scans, an independent report on these was not valid. The report obtained from the site was used to determine the tear status. Any re-tears were not reported to the participating surgeons, so that no deviation occurred from their normal practice.

Statistical analysis of outcomes

Statistical analyses were based on all people randomised, irrespective of subsequent compliance with the randomised intervention. The principal comparison was all those allocated arthroscopic surgery compared with all those allocated open surgery. When an effect size is shown for the intervention, a negative sign on the effect size indicates that an open procedure is favoured over an arthroscopic procedure.

Reflecting the possible clustering in the data, the outcomes were compared using repeated-measures mixed models with centre as a random effect and with adjustment for minimisation variables (size of tear and age) and participant baseline values (when available) as fixed effects. Statistical significance was at the 5% level, with corresponding confidence intervals (CIs) derived. All participants remained in their allocated group for analysis (ITT).

Preplanned subgroup analyses on the primary outcome included exploration of tear size (small/medium vs. large/massive) and age (≤ 65 years vs. > 65 years); these analyses were conducted by including a subgroup by treatment interaction term in the primary outcome model described above. Conservative levels of statistical significance ($p < 0.01$) were sought, reflecting the exploratory nature of these subgroup analyses.

Non-response analysis

Descriptive data comparing the baseline characteristics of participants who did and did not respond at 24 months were displayed. The *t*-test (continuous outcomes) and chi-squared test (dichotomous outcomes) were used to estimate the statistical significance of the differences between responders and non-responders.

Sensitivity analysis: treatment received (per protocol)

Reflecting the level of non-compliance, the effect on the primary outcome of those participants who actually received an arthroscopic or open repair was estimated. In an open trial design a per-protocol analysis can have substantial selection bias. To minimise the effects of selection bias we used the instrumental variable approach as described by Nagelkerke *et al.*[69] The method used a two-stage least-squares approach whereby

treatment randomised was regressed onto treatment received and the residuals from that model were used as an independent variable in a second model, together with the treatment received, to estimate the effects on the primary outcome measure. As with the ITT analysis, the model also adjusted for centre, minimisation variables (age, size of tear) and baseline OSS score.

Learning curve

The main analyses adjusted for centre effects and therefore adjusted for the majority of differences between centres. Learning effects may, however, be present in the trial (i.e. the surgeon's performance improves throughout the trial). To test for these effects a covariate for each surgeon was developed that indicates the increasing surgeon experience in the trial (e.g. first patient randomised = 1; second = 2, etc.). This covariate was used in subsequent adjusted analyses to measure the size of the trend in effects over time.

Health economics methods

A cost-effectiveness analysis was performed. A simple patient cost-related questionnaire was sent out at baseline and at 12 and 24 months post randomisation to obtain information on primary care consultations, other consultations, out-of pocket costs, the work impact of the intervention received and return to work (when relevant). Although longer intervals between questionnaires may result in recall errors (in particular under-reporting of health-care use[70]) more frequent data collection can result in a higher proportion of missing responses, which introduces uncertainty. It has been argued that there is no optimal interval for self-reported data collection[70] and as such the timing of questionnaire distribution was chosen to coincide with those for the clinical study outcomes. Unit costs came from national sources and participating hospitals. The patient questionnaire was also used to administer the European Quality of Life-5 Dimensions (EQ-5D), which was obtained at baseline. The main health economic outcome was within-trial and extrapolated QALYs, estimated using the EQ-5D.[71]

Incremental cost-effectiveness was calculated as the net cost per QALY gained for arthroscopic surgery compared with open surgery. Power calculations (see following section) were based on clinical effectiveness rather than cost-effectiveness outcomes, which were estimated rather than used in hypothesis testing. Cost-effectiveness ratios and acceptability curves were calculated.

An important component of this trial was the assessment of cost. Therefore, obtaining an accurate record of procedures at each of the proposed centres was essential. To evaluate the costs of each type of surgery, information was collected from the operating theatres. Resources used, equipment costs and standard procedures for rotator cuff repairs were examined. Per-case information was also analysed. A checklist of equipment, consumables, implants, time and staff utilised during each case was completed by theatre staff. Information from theatres was collected by the Oxford office and used in a cost comparison of the arthroscopic and open surgery approaches.

Sample size

In the original UKUFF trial, with three randomised strata, the sample size was constructed to detect a difference in the OSS 24-month postoperative score of 0.38 of a standard deviation (SD) for the comparison between arthroscopic surgery and open surgery at 80% power. We did not propose any amendment to that clinically important difference in the reconfigured study. This defined difference was based on our experience of developing the OSS score and using it in a variety of settings; a 3-point score difference (0.33 of a SD) was deemed a clinically important difference. In the original UKUFF trial, the detectable difference of 0.38 was constructed by combining evidence from a direct randomised comparison with indirect (non-randomised) comparison data from the other strata. Incorporating indirect effects is a suboptimal approach to measuring effectiveness because unmeasured confounders can bias the outcomes. The proposed change in this proposal was to achieve the detectable difference of 0.38 of a SD

by direct randomised comparison data only at 85% power. As described earlier, such an approach was feasible by 2010 because of the increased number of surgeons in equipoise between the arthroscopic approach and the open approach.

Attrition was expected to be low (10%), as were the effects of clustering of outcomes by surgeon [intracluster correlation (ICC) < 0.03].[72,73] Although we did not have a direct estimate from a shoulder trial, other orthopaedic data sets available to our team support this low ICC estimate. Both of these factors required the sample size to be inflated; however, the primary analysis adjusted for baseline OSS score, which conversely allowed the sample size to be decreased by a factor of (1 – correlation squared).[74] Our previous studies showed that the correlation in the OSS score pre surgery to 6 months post surgery in patients similar to the potential trial participants was 0.57. Assuming a conservative correlation of 0.5 implied that the sample size could be reduced by 25% and still maintain the same power. Therefore, a study with a total of 267 participants would still have 85% power to detect a clinically important difference in each comparison, assuming that attrition and clustering accounted for approximately 25% of variation in the data.

Data monitoring

An independent DMC met on four occasions and did not recommend any fundamental changes to the protocol. The decision in 2009 to reconfigure the trial was made by the NIHR HTA programme. The committee did not meet after recruitment was completed.

Chapter 3 Description of the study population

This chapter describes the derivation of the populations that took part in the UKUFF study, the characteristics of the participants at presurgical assessment and the baseline characteristics of included participants.

Recruitment to the study

Participants were recruited in 47 clinical centres, all within the UK (*Table 3*). Nineteen centres recruited to the randomised arthroscopic surgery and randomised open surgery comparison (referred to as the stratum A comparison). Thirteen of these centres also randomised participants to stratum A prior to reconfiguration of the study in December 2010 (see *Chapter 2*). Twenty centres recruited to stratum B (arthroscopic surgery vs. rest then exercise) and 18 to stratum C (open surgery vs. rest then exercise). A total of 660 participants were recruited to the study, with 317 in stratum A ($n = 136$, allocated to arthroscopic surgery; $n = 137$, allocated to open surgery; and $n = 44$, allocated to rest then exercise prior to reconfiguration), 181 in stratum B ($n = 91$, allocated to arthroscopic surgery; and $n = 90$, allocated to rest then exercise prior to reconfiguration) and 162 in stratum C ($n = 82$, allocated to open surgery; and $n = 80$, allocated to rest then exercise prior to reconfiguration). *Table 3* shows recruitment by centre. No centre contributed more than 12% of participants to stratum A. Recruitment to the trial began on 9 November 2007 and continued until 28 February 2012, although not all centres enrolled over the total period because of the staggered introduction of centres and early closure for reconfiguration of the study (range 6 months to 39 months from first to last participant randomised in stratum A). Data were closed to follow-up on 31 December 2013.

TABLE 3 Recruitment by centre

Centre	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)		Total (*n* = 660)	Randomised to stratum A prior to reconfiguration	Length of time randomising to stratum A
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)			
University Hospitals of Leicester NHS Trust	16 (11.8)	17 (12.4)	4 (9.1)			4 (4.9)	3 (3.8)	44 (6.67)	Yes	3 years 0 months
Worcestershire Acute Hospitals NHS Trust	16 (11.8)	16 (11.7)	4 (9.1)					36 (5.45)	Yes	2 years 8 months
Gwent Healthcare NHS Trust	13 (9.6)	13 (9.5)	5 (11.4)					31 (4.70)	Yes	3 years 3 months
Nuffield Orthopaedic Centre	15 (11.0)	15 (10.9)				18 (22.0)	18 (22.5)	66 (10.00)	No	1 years 4 months
Ipswich Hospital NHS Trust	12 (8.8)	13 (9.5)	4 (9.1)					29 (4.39)	Yes	2 years 11 months
University Hospitals Coventry and Warwickshire NHS Trust	8 (5.9)	9 (6.6)	7 (15.9)			3 (3.7)	4 (5.0)	31 (4.70)	Yes	2 years 11 months
South Tees Hospitals NHS Foundation Trust	9 (6.6)	8 (5.8)	4 (9.1)					21 (3.18)	Yes	2 years 9 months
Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Foundation Trust	7 (5.1)	6 (4.4)	6 (13.6)	1 (1.1)		1 (1.2)	2 (2.5)	23 (3.48)	Yes	2 years 7 months
Maidstone and Tunbridge Wells NHS Trust	8 (5.9)	8 (5.8)	2 (4.5)					18 (2.73)	Yes	2 years 2 months
Surrey and Sussex Healthcare NHS Trust	8 (5.9)	9 (6.6)		11 (12.1)	10 (11.1)			38 (5.76)	No	1 years 3 months
Dudley Group NHS Foundation Trust	7 (5.1)	6 (4.4)	3 (6.8)					16 (2.42)	Yes	2 years 5 months
Pennine Acute Hospitals NHS Trust	4 (2.9)	4 (2.9)	2 (4.5)					10 (1.52)	Yes	2 years 8 months
Swansea NHS Trust	3 (2.2)	5 (3.6)	2 (4.5)					10 (1.52)	Yes	3 years 3 months

Centre	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)		Total (*n* = 660)	Randomised to stratum A prior to reconfiguration	Length of time randomising to stratum A
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)			
University Hospital Southampton NHS Foundation Trust	3 (2.2)	4 (2.9)				8 (9.8)	8 (10.0)	23 (3.48)	No	0 years 2 months
North Bristol NHS Trust	2 (1.5)	1 (0.7)	1 (2.3)					4 (0.61)	Yes	0 years 11 months
East Lancashire Hospitals NHS Trust	2 (1.5)	1 (0.7)			1 (1.1)			4 (0.61)	No	1 years 2 months
Barnet and Chase Farm NHS Trust	1 (0.7)	1 (0.7)		1 (1.1)	1 (1.1)			4 (0.61)	No	0 years 6 months
Basingstoke and North Hampshire Hospitals NHS Trust	1 (0.7)	1 (0.7)		1 (1.1)				3 (0.45)	Yes	1 years 1 months
Sheffield Teaching Hospitals NHS Foundation Trust	1 (0.7)							1 (0.15)	No	0 years 1 months
Basildon and Thurrock University Hospitals NHS Foundation Trust						5 (6.1)	4 (5.0)	9 (1.36)	No	NA
Buckinghamshire Healthcare NHS Trust				6 (6.6)	6 (6.7)			12 (1.82)	No	NA
Derby Teaching Hospitals NHS Foundation Trust				3 (3.3)	5 (5.6)			8 (1.21)	No	NA
Epsom and St Helier University Hospitals NHS Trust				15 (16.5)	15 (16.7)			30 (4.55)	No	NA
Forth Valley Acute Operating Division						2 (2.4)	2 (2.5)	4 (0.61)	No	NA
Frimley Park Hospital NHS Foundation Trust				1 (1.1)	1 (1.1)			2 (0.30)	No	NA

continued

TABLE 3 Recruitment by centre (*continued*)

Centre	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)		Total (*n* = 660)	Randomised to stratum A prior to reconfiguration	Length of time randomising to stratum A
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)			
Guy's and St Thomas' NHS Foundation Trust				1 (1.1)	2 (2.2)			3 (0.45)	No	NA
Heatherwood and Wexham Park Hospitals NHS Foundation Trust						2 (2.4)	2 (2.5)	4 (0.61)	No	NA
Hereford Hospitals NHS Trust						5 (6.1)	4 (5.0)	9 (1.36)	No	NA
Lancashire Teaching Hospitals NHS Trust				1 (1.1)	1 (1.1)			2 (0.30)	No	NA
Lothian University Hospitals Division				8 (8.8)	9 (10.0)			17 (2.58)	No	NA
Mid Essex Hospital Services NHS Trust						2 (2.4)	1 (1.3)	3 (0.45)	No	NA
Mid Staffordshire General Hospitals NHS Trust						2 (2.4)	2 (2.5)	4 (0.61)	No	NA
Mid Yorkshire Hospitals NHS Trust				5 (5.5)	5 (5.6)			10 (1.52)	No	NA
Milton Keynes Hospital NHS Foundation Trust						2 (2.4)	1 (1.3)	3 (0.45)	No	NA
Norfolk and Norwich University Hospitals NHS Foundation Trust						5 (6.1)	6 (7.5)	11 (1.67)	No	NA
North Cumbria Acute Hospitals NHS Trust						4 (4.9)	4 (5.0)	8 (1.21)	No	NA
Plymouth Hospitals NHS Trust						3 (3.7)	3 (3.8)	6 (0.91)	No	NA

Centre	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)		Total (*n* = 660)	Randomised to stratum A prior to reconfiguration	Length of time randomising to stratum A
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)			
Queen Elizabeth Hospital NHS Trust				1 (1.1)				1 (0.15)	No	NA
Royal Berkshire NHS Foundation Trust				5 (5.5)	4 (4.4)			9 (1.36)	No	NA
Royal Devon and Exeter NHS Foundation Trust						3 (3.7)	3 (3.8)	6 (0.91)	No	NA
Royal Free Hampstead NHS Trust				4 (4.4)	3 (3.3)			7 (1.06)	No	NA
Salford Royal NHS Foundation Trust				4 (4.4)	4 (4.4)			8 (1.21)	No	NA
South Devon Healthcare NHS Foundation Trust						8 (9.8)	8 (10.0)	16 (2.42)	No	NA
St George's Healthcare NHS Trust				5 (5.5)	4 (4.4)			9 (1.36)	No	NA
Stockport NHS Foundation Trust				2 (2.2)	2 (2.2)			4 (0.61)	No	NA
Trafford Healthcare NHS Trust				16 (17.6)	17 (18.9)			33 (5.00)	No	NA
Yeovil District Hospital NHS Foundation Trust						5 (6.1)	5 (6.3)	10 (1.52)	No	NA

NA, not applicable.

Study conduct

The derivation of the main study groups and their progress through the stages of follow-up in the trial is shown in *Figure 1* This is in the form of a Consolidated Standards of Reporting Trials (CONSORT) flow diagram. In total, 811 patients were considered for trial entry and 38 (5%) of these were found not to meet one or more of the eligibility criteria. Of the 111 patients eligible for the study but not recruited, 84 declined to participate and the remaining 27 could not be randomised while the study underwent reconfiguration (because of the requirement for new research ethics and research and development approvals). Two participants were excluded post randomisation because each had received previous surgery prior to randomisation. Details of the clinical management actually received are provided in *Chapter 4*. The median [interquartile range (IQR)] time intervals in days between randomisation by the trial office and each subsequent follow-up are shown in *Table 4*; all were similar between groups, as would be expected. The 2-week and 8-week follow-ups were timed to occur at 2 weeks and 8 weeks after surgery. *Table 5* illustrates the success of this strategy in the subgroup of participants who did receive a surgical procedure.

The overall rates of return of follow-up questionnaires at 8, 12 and 24 months were equivalent to > 85% of the study participants allocated to surgery (see *Figure 1*). There were no substantive differences in response rates between the surgery groups. Seven participants are known to have died by the end of the 2-year follow-up. There was no evidence that these deaths were linked to trial participation.

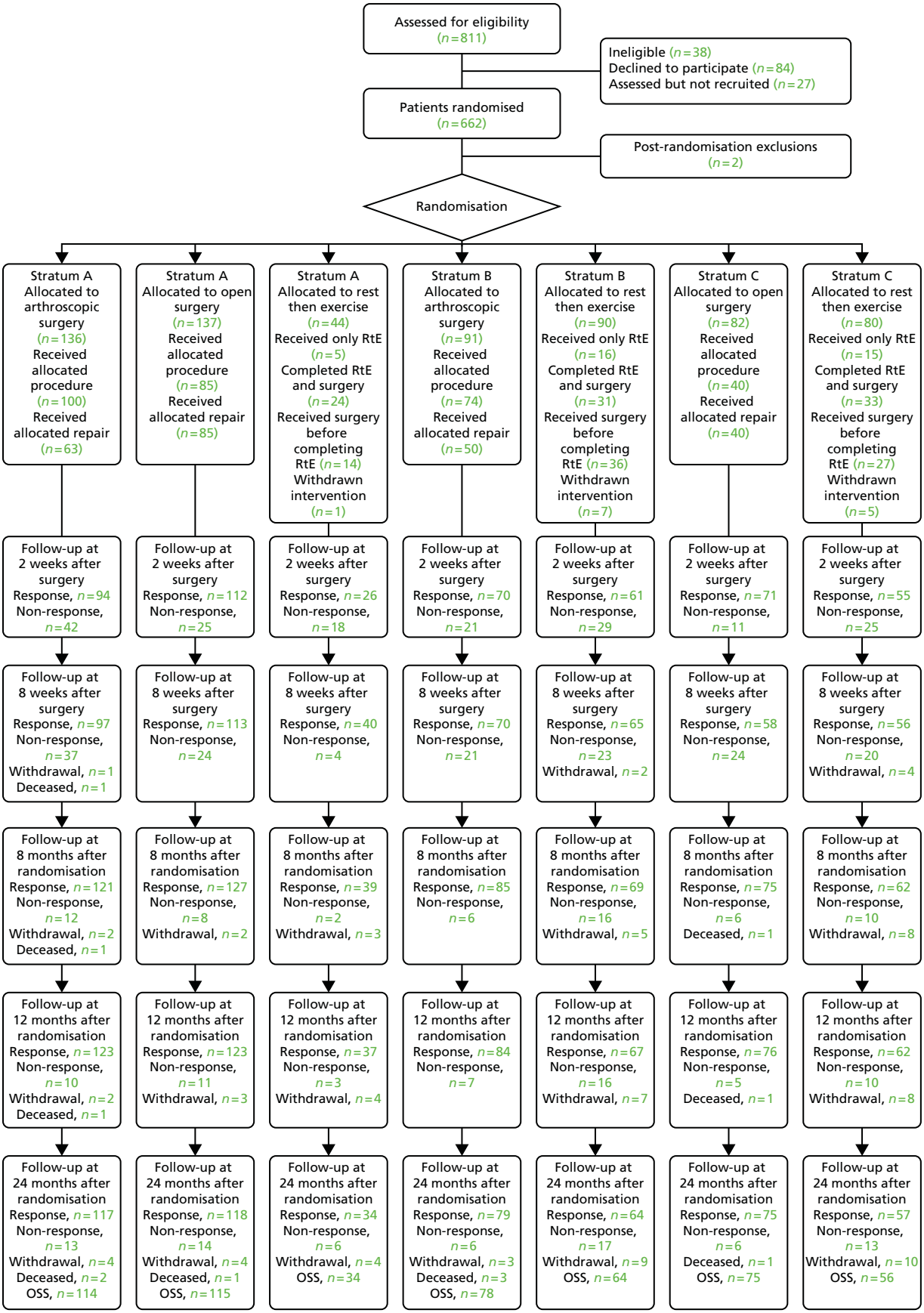

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) diagram. RtE, rest then exercise.

TABLE 4 Median (IQR) number of days between randomisation and follow-up

	Stratum A			Stratum B		Stratum C	
Follow-up	Arthroscopic ($n = 136$)	Open ($n = 137$)	Rest then exercise ($n = 44$)	Arthroscopic ($n = 91$)	Rest then exercise ($n = 90$)	Open ($n = 82$)	Rest then exercise ($n = 80$)
2 weeks	99 (65–137)	97 (65–134)	93 (63–126)	82 (62–108)	99 (65–126)	87 (60–129)	101 (75–126)
8 weeks	135 (105–169)	139 (102–178)	149 (114–181)	126 (106–152)	134 (110–162)	142 (107–177)	141 (113–167)
8 months	231 (227–248)	230 (227–236)	232 (228–244)	231 (227–248)	232 (227–245)	229 (227–239)	234 (228–246)
12 months	374 (369–387)	373 (369–383)	371 (369–389)	374 (370–383)	375 (369–389)	371 (368–378)	372 (369–386)
24 months	737 (733–745)	736 (733–745)	740 (734–754)	738 (734–754)	739 (733–754)	736 (734–752)	736 (733–746)

TABLE 5 Median (IQR) number of days between surgery and follow-up

	Stratum A		Stratum B	Stratum C
Follow-up	Arthroscopic ($n = 100$)	Open ($n = 114$)	Arthroscopic ($n = 74$)	Open ($n = 68$)
2 weeks	14 (14–16)	14 (14–15)	14 (14–16)	14 (14–15)
8 weeks	56 (56–59)	56 (56–58)	57 (56–61)	57 (56–60)
8 months	161 (117–194)	155 (122–188)	169 (147–201)	164 (122–197)
12 months	307 (258–336)	296 (262–335)	316 (292–342)	306 (259–333)
24 months	656 (620–693)	654 (622–699)	682 (647–708)	672 (623–712)

Description of the groups at trial entry

Clinical assessment at baseline

Table 6 displays the results of the presurgical assessment at recruitment. Approximately two-thirds of the tears were diagnosed using ultrasound. Tears were small or medium in about 75% of the participants in strata A and C and in 58% of participants in stratum B. Within the randomised groups there were no apparent imbalances. Around 10% of participants had received no previous treatment to their shoulder. Previous treatments primarily included physiotherapy and/or cortisone injections.

TABLE 6 Clinical assessment at baseline

	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)	
Assessment	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
Size of tear							
Small/medium	103 (75.7)	103 (75.2)	34 (77.3)	53 (58.2)	52 (57.8)	62 (75.6)	62 (77.5)
Large/massive	33 (24.3)	34 (24.8)	10 (22.7)	38 (41.8)	38 (42.2)	20 (24.4)	18 (22.5)
Method of diagnosing tear							
MRI	41 (30.1)	36 (26.3)	9 (20.5)	20 (22.0)	20 (22.2)	19 (23.2)	12 (15.0)
Ultrasound	87 (64.0)	93 (67.9)	32 (72.7)	64 (70.3)	60 (66.7)	60 (73.2)	56 (70.0)
Missing	8 (5.9)	8 (5.8)	3 (6.8)	7 (7.7)	10 (11.1)	3 (3.7)	12 (15.0)
Received no treatment on shoulder in the last 5 years	15 (11.0)	10 (7.3)	2 (4.5)	9 (9.9)	9 (10.0)	3 (3.7)	8 (10.0)
Received physiotherapy on affected shoulder in the last 5 years							
Yes	77 (56.6)	83 (60.6)	28 (63.6)	54 (59.3)	64 (71.1)	59 (72.0)	49 (61.3)
No	41 (30.1)	38 (27.7)	10 (22.7)	22 (24.2)	21 (23.3)	12 (14.6)	23 (28.8)
Missing	18 (13.2)	16 (11.7)	6 (13.6)	15 (16.5)	5 (5.6)	11 (13.4)	8 (10.0)
Duration of physiotherapy (weeks)							
≤ 4	17 (22.1)	20 (24.1)	7 (25.0)	10 (11.0)	13 (20.3)	16 (27.1)	10 (20.4)
5–12	24 (31.2)	22 (26.5)	11 (39.3)	15 (16.5)	18 (28.1)	17 (28.8)	13 (26.5)
> 12	19 (24.7)	21 (25.3)	8 (28.6)	21 (23.1)	19 (29.7)	16 (27.1)	13 (26.5)
Missing	17 (22.1)	20 (24.1)	2 (7.1)	45 (49.5)	14 (21.9)	10 (16.9)	13 (26.5)
Received an injection in affected shoulder in the last 5 years							
Yes	79 (58.1)	83 (60.6)	30 (68.2)	52 (57.1)	46 (51.1)	59 (72.0)	53 (66.3)
No	40 (29.4)	35 (25.5)	9 (20.5)	25 (27.5)	34 (37.8)	14 (17.1)	21 (26.3)
Missing	17 (12.5)	19 (13.9)	5 (11.4)	14 (15.4)	10 (11.1)	9 (11.0)	6 (7.5)

continued

TABLE 6 Clinical assessment at baseline (*continued*)

Assessment	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
Number of injections							
1	34 (43.0)	35 (42.2)	14 (46.7)	26 (50.0)	24 (52.2)	25 (42.4)	21 (39.6)
2	21 (26.6)	29 (34.9)	8 (26.7)	13 (25.0)	10 (21.7)	17 (28.8)	16 (30.2)
3	10 (12.7)	10 (12.0)	4 (13.3)	9 (17.3)	5 (10.9)	8 (13.6)	6 (11.3)
4	3 (3.8)	2 (2.4)		1 (1.9)	2 (4.3)	2 (3.4)	3 (5.7)
5	2 (2.5)	1 (1.2)	1 (3.3)			2 (3.4)	1 (1.9)
6	1 (1.3)	3 (3.6)		1 (1.9)	1 (2.2)		1 (1.9)
7	1 (1.3)					1 (1.7)	1 (1.9)
9						1 (1.7)	
10				1 (1.9)			
Missing	7 (8.9)	3 (3.6)	3 (10.0)	1 (1.9)	4 (8.7)	3 (5.1)	4 (7.5)
Received other treatment on the affected shoulder in the last 5 years							
Yes	18 (13.2)	28 (20.4)	5 (11.4)	5 (5.5)	2 (2.2)	16 (19.5)	13 (16.3)
No	72 (52.9)	61 (44.5)	20 (45.5)	43 (47.3)	48 (53.3)	36 (43.9)	32 (40.0)
Missing	46 (33.8)	48 (35.0)	19 (43.2)	43 (47.3)	40 (44.4)	30 (36.6)	35 (43.8)
Other treatment							
Acupuncture	2 (11.1)	5 (17.9)	3 (60.0)	3 (60.0)		5 (31.3)	5 (38.5)
Analgesics	6 (33.3)	13 (46.4)	1 (20.0)			1 (6.3)	
Chiropractor	3 (16.7)	2 (7.1)		1 (20.0)		5 (31.3)	2 (15.4)
Exercises		2 (7.1)			1 (50.0)		
Hydrotherapy	2 (11.1)						
Massage						1 (6.3)	
Nerve block	1 (5.6)						
Osteopathy		1 (3.6)			1 (50.0)	1 (6.3)	2 (15.4)
TENS	1 (5.6)	2 (7.1)	1 (20.0)			1 (6.3)	
Ultrasound		1 (3.6)					3 (23.1)
Missing	3 (16.7)	2 (7.1)		1 (20.0)		2 (12.5)	1 (7.7)
Are there any problems with other shoulder?							
No problems	84 (61.8)	86 (62.8)	27 (61.4)	49 (53.8)	64 (71.1)	47 (57.3)	49 (61.3)
Mild problems	32 (23.5)	29 (21.2)	9 (20.5)	24 (26.4)	11 (12.2)	23 (28.0)	22 (27.5)
Moderate problems	11 (8.1)	12 (8.8)	3 (6.8)	14 (15.4)	11 (12.2)	9 (11.0)	7 (8.8)
Severe problems	4 (2.9)	5 (3.6)	2 (4.5)	2 (2.2)	3 (3.3)	1 (1.2)	
Missing	5 (3.7)	5 (3.6)	3 (6.8)	2 (2.2)	1 (1.1)	2 (2.4)	2 (2.5)

TENS, transcutaneous electrical nerve stimulation.

Participant and sociodemographic factors

Participant and sociodemographic characteristics are shown in *Table 7*. The average age of the participants was 63 years, 40% were female and 90% were right-handed. The mean period of time that the participants reported having the shoulder problem prior to surgery was approximately 2.5 years; however, the mean was driven by a few extreme values in each group relating to participants who had had shoulder problems for decades. The median (IQR) time that the participants had had the shoulder problem prior to recruitment was 1.2 (0.7–2.5) years. There were no substantive differences within or between strata on any of the sociodemographic factors.

TABLE 7 Participant and sociodemographic characteristics at baseline

Characteristic	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
Age (years), *n*, mean (SD)	136, 62.9 (7.1)	137, 62.9 (7.5)	44, 62.9 (7.5)	91, 65.7 (7.9)	90, 64.7 (8.0)	82, 61.9 (6.5)	80, 61.3 (6.8)
Years with shoulder problem, *n*, mean (SD)	136, 2.6 (5.3)	137, 2.5 (4.1)	43, 2.0 (2.7)	90, 2.5 (3.4)	87, 2.2 (3.3)	82, 2.7 (4.7)	79, 2.3 (2.6)
Sex							
Male	81 (59.6)	88 (64.2)	28 (63.6)	53 (58.2)	63 (70.0)	49 (59.8)	51 (63.8)
Female	55 (40.4)	49 (35.8)	16 (36.4)	36 (39.6)	27 (30.0)	33 (40.2)	29 (36.3)
Missing				2 (2.2)			
Handedness							
Right-handed	125 (91.9)	115 (83.9)	40 (90.9)	83 (91.2)	78 (86.7)	66 (80.5)	66 (82.5)
Left-handed	7 (5.1)	17 (12.4)	1 (2.3)	8 (8.8)	9 (10.0)	11 (13.4)	8 (10.0)
Both	4 (2.9)	5 (3.6)	2 (4.5)		3 (3.3)	4 (4.9)	5 (6.3)
Missing			1 (2.3)			1 (1.2)	1 (1.3)
Highest qualification							
None	63 (46.3)	59 (43.1)	23 (52.3)	39 (42.9)	37 (41.1)	34 (41.5)	25 (31.3)
Secondary	41 (30.1)	49 (35.8)	16 (36.4)	37 (40.7)	38 (42.2)	33 (40.2)	41 (51.3)
Higher	32 (23.5)	27 (19.7)	5 (11.4)	12 (13.2)	12 (13.3)	15 (18.3)	12 (15.0)
Missing		2 (1.5)		3 (3.3)	3 (3.3)		2 (2.5)
Housing tenure							
Home owner	107 (78.7)	119 (86.9)	34 (77.3)	78 (85.7)	78 (86.7)	69 (84.1)	68 (85.0)
Private rent	7 (5.1)	1 (0.7)	3 (6.8)	3 (3.3)	2 (2.2)	5 (6.1)	4 (5.0)
Council rent	17 (12.5)	9 (6.6)	5 (11.4)	7 (7.7)	7 (7.8)	5 (6.1)	2 (2.5)
Other	4 (2.9)	8 (5.8)	2 (4.5)	2 (2.2)	2 (2.2)	3 (3.7)	5 (6.3)
Missing	1 (0.7)			1 (1.1)	1 (1.1)		1 (1.3)

continued

TABLE 7 Participant and sociodemographic characteristics at baseline (*continued*)

Characteristic	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
Lives alone							
Yes	23 (16.9)	12 (8.8)	6 (13.6)	15 (16.5)	19 (21.1)	14 (17.1)	12 (15.0)
No	101 (74.3)	118 (86.1)	34 (77.3)	74 (81.3)	67 (74.4)	66 (80.5)	64 (80.0)
Missing	12 (8.8)	7 (5.1)	4 (9.1)	2 (2.2)	4 (4.4)	2 (2.4)	4 (5.0)
Employment status							
Full-time	47 (34.6)	58 (42.3)	12 (27.3)	22 (24.2)	30 (33.3)	28 (34.1)	35 (43.8)
Part-time	18 (13.2)	15 (10.9)	7 (15.9)	13 (14.3)	10 (11.1)	13 (15.9)	8 (10.0)
Homemaker	4 (2.9)	5 (3.6)		3 (3.3)		2 (2.4)	
Retired	59 (43.4)	54 (39.4)	22 (50.0)	52 (57.1)	45 (50.0)	36 (43.9)	32 (40.0)
Unemployed	7 (5.1)	4 (2.9)	3 (6.8)	1 (1.1)	5 (5.6)	3 (3.7)	4 (5.0)
Missing	1 (0.7)	1 (0.7)					1 (1.3)
Type of work							
Manual	36 (55.4)	41 (56.2)	12 (63.2)	22 (62.9)	27 (67.5)	24 (58.5)	24 (55.8)
Non-manual	26 (40.0)	28 (38.4)	6 (31.6)	12 (34.3)	11 (27.5)	16 (39.0)	15 (34.9)
Not sure	3 (4.6)	3 (4.1)	1 (5.3)	1 (2.9)	1 (2.5)	1 (2.4)	3 (7.0)
Missing		1 (1.4)			1 (2.5)		1 (2.3)
Off sick or working reduced duties							
Yes, off sick	7 (10.8)	6 (8.2)	3 (15.8)	2 (5.7)	5 (12.5)	3 (7.3)	4 (9.3)
Yes, working reduced duties	10 (15.4)	7 (9.6)	5 (26.3)	5 (14.3)	8 (20.0)	9 (22.0)	8 (18.6)
No	45 (69.2)	58 (79.5)	11 (57.9)	28 (80.0)	27 (67.5)	29 (70.7)	31 (72.1)
Missing	3 (4.6)	2 (2.8)					
Would you be able to do your job or everyday activities with your arm in a sling?							
No	70 (51.5)	76 (55.5)	18 (40.9)	51 (56.0)	48 (53.3)	41 (50.0)	43 (53.8)
Yes, with difficulty	62 (45.6)	59 (43.1)	19 (43.2)	39 (42.9)	35 (38.9)	39 (47.6)	31 (38.8)
Yes, no difficulty	3 (2.2)	1 (0.7)	4 (9.1)	1 (1.1)	2 (2.2)		5 (6.3)
Missing	1 (0.7)	1 (0.7)	3 (6.8)		5 (5.6)	2 (2.4)	1 (1.3)

Health status

The health-related quality-of-life measures are shown in *Table 8*. The mean OSS was approximately 26 across the groups. The EQ-5D, MHI-5 and SPADI measures were broadly similar across and within the strata.

TABLE 8 Health status at baseline

	Stratum A, *n*, mean (SD)			Stratum B, *n*, mean (SD)		Stratum C, *n*, mean (SD)	
Measure	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
OSS	136, 26.2 (8.1)	137, 25.2 (7.9)	44, 23.7 (8.3)	91, 25.3 (8.9)	90, 23.5 (8.0)	82, 25.9 (8.4)	80, 26.2 (7.9)
SPADI	136, 60.9 (22.0)	136, 61.6 (22.0)	44, 66.9 (22.1)	91, 60.6 (23.1)	90, 67.8 (20.4)	82, 60.7 (20.1)	79, 62.3 (20.1)
SPADI pain	136, 70.0 (19.5)	137, 70.1 (20.5)	44, 73.0 (22.0)	91, 70.0 (21.8)	89, 73.1 (19.4)	82, 69.6 (19.5)	80, 69.4 (18.2)
SPADI disability	136, 55.1 (25.0)	135, 56.4 (24.7)	44, 63.0 (23.7)	91, 54.7 (25.9)	90, 64.4 (22.1)	82, 55.2 (21.9)	77, 57.7 (23.3)
MHI-5	136, 22.5 (4.9)	137, 22.9 (4.5)	44, 21.5 (5.5)	90, 22.4 (5.1)	90, 22.7 (4.9)	82, 22.1 (4.7)	80, 22.9 (4.6)
EQ-5D	135, 0.548 (0.299)	136, 0.519 (0.291)	43, 0.448 (0.332)	91, 0.514 (0.326)	89, 0.503 (0.287)	81, 0.536 (0.287)	79, 0.538 (0.298)

Attitudes to surgery

As expected, there was variation in participants' attitudes to undergoing surgery in general, but the variation was not different between groups (*Table 9*).

TABLE 9 Attitudes to surgery

Question	Stratum A, *n* (%)			Stratum B, *n* (%)		Stratum C, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Rest then exercise (*n* = 44)	Arthroscopic (*n* = 91)	Rest then exercise (*n* = 90)	Open (*n* = 82)	Rest then exercise (*n* = 80)
To what extent do you agree that doctors rely on surgery too much?							
Strongly agree				2 (2.2)			
Agree	3 (2.2)	3 (2.2)	3 (6.8)	6 (6.6)	5 (5.6)	1 (1.2)	5 (6.3)
Uncertain	52 (38.2)	51 (37.2)	26 (59.1)	40 (44.0)	35 (38.9)	26 (31.7)	29 (36.3)
Disagree	72 (52.9)	76 (55.5)	13 (29.5)	35 (38.5)	42 (46.7)	52 (63.4)	39 (48.8)
Strongly disagree	7 (5.1)	4 (2.9)	2 (4.5)	7 (7.7)	7 (7.8)	2 (2.4)	5 (6.3)
Missing	2 (1.5)	3 (2.2)		1 (1.1)	1 (1.1)	1 (1.2)	2 (2.5)
To what extent do you agree that doctors place too much trust in surgery?							
Strongly agree		1 (0.7)	1 (2.3)	2 (2.2)			
Agree	6 (4.4)	4 (2.9)	9 (20.5)	9 (9.9)	7 (7.8)	1 (1.2)	8 (10.0)
Uncertain	66 (48.5)	61 (44.5)	22 (50.0)	47 (51.6)	35 (38.9)	39 (47.6)	33 (41.3)
Disagree	54 (39.7)	62 (45.3)	11 (25.0)	27 (29.7)	43 (47.8)	36 (43.9)	33 (41.3)
Strongly disagree	9 (6.6)	5 (3.6)	1 (2.3)	5 (5.5)	4 (4.4)	3 (3.7)	3 (3.8)
Missing	1 (0.7)	4 (2.9)		1 (1.1)	1 (1.1)	3 (3.7)	3 (3.8)
To what extent do you agree that you worry about surgery risks?							
Strongly agree	5 (3.7)	5 (3.6)	3 (6.8)	13 (14.3)	12 (13.3)	2 (2.4)	4 (5.0)
Agree	58 (42.6)	51 (37.2)	20 (45.5)	37 (40.7)	35 (38.9)	30 (36.6)	33 (41.3)
Uncertain	21 (15.4)	18 (13.1)	8 (18.2)	13 (14.3)	14 (15.6)	22 (26.8)	16 (20.0)
Disagree	43 (31.6)	49 (35.8)	12 (27.3)	23 (25.3)	23 (25.6)	22 (26.8)	20 (25.0)
Strongly disagree	8 (5.9)	12 (8.8)	1 (2.3)	(5.5)	4 (4.4)	3 (3.7)	4 (5.0)
Missing	1 (0.7)	2 (1.5)			2 (2.2)	3 (3.7)	3 (3.8)
To what extent do you agree that surgery should be only a last resort?							
Strongly agree	17 (12.5)	19 (13.9)	6 (13.6)	20 (22.0)	12 (13.3)	11 (13.4)	11 (13.8)
Agree	75 (55.1)	67 (48.9)	17 (38.6)	41 (45.1)	48 (53.3)	38 (46.3)	36 (45.0)
Uncertain	19 (14.0)	24 (17.5)	9 (20.5)	14 (15.4)	12 (13.3)	16 (19.5)	13 (16.3)
Disagree	23 (16.9)	22 (16.1)	11 (25.0)	9 (9.9)	15 (16.7)	13 (15.9)	15 (18.8)
Strongly disagree	1 (0.7)	4 (2.9)	1 (2.3)	7 (7.7)	3 (3.3)	2 (2.4)	2 (2.5)
Missing	1 (0.7)	1 (0.7)				2 (2.4)	3 (3.8)

Summary

There was no evidence of any important imbalances between the groups. With a mean OSS of around 26, the population was representative of those in other shoulder studies (see *Chapter 1*). Most participants had undergone some form of non-surgical intervention (such as physiotherapy) before the trial and had had symptoms for over a year. In *Chapter 4*, the results of the randomised trial of arthroscopic compared with open surgery will be reported. A description of the findings from the rest-then-exercise programme will be provided in *Chapter 5*.

Chapter 4 Results: arthroscopic surgery compared with open surgery

This chapter describes the comparison between arthroscopic surgery and open surgery and includes operative characteristics and outcomes at 2 and 8 weeks post surgery as well as 8, 12 and 24 months after randomisation.

Analysis populations

Throughout the analyses presented in this chapter, the participants in the formal randomised comparison between arthroscopic surgery and open surgery (stratum A) are kept separate from those in the arthroscopic and open groups in strata B and C respectively. All 273 participants who joined the randomised arthroscopic compared with open surgery component in stratum A are referred to as the *randomised ITT population*; the 148 ($n = 63$ arthroscopic; $n = 85$ open) within this group who actually received a repair over the 2-year follow-up period are referred to as the *per-protocol population*. The *non-randomised population* refers to the 91 participants allocated to arthroscopic surgery from stratum B and the 82 participants allocated to open surgery in stratum C (included in this chapter for completeness and visual inspection of data). No statistical analysis is performed on the non-randomised population.

Surgical management

Randomised intention-to-treat population

Table 10 shows the types of procedure undertaken in each group. For the 136 participants randomised to receive arthroscopic surgical management, 63 (46.3%) underwent an arthroscopic repair of a tear, nine (6.6%) began as an arthroscopic procedure and converted to an open repair, 28 (20.6%) underwent an arthroscopic procedure (that did not involve a repair of a tear) and 36 (26.5%) withdrew and did not undergo any surgery. Of the arthroscopic procedures not involving a repair, a shoulder subacromial decompression was the most common procedure undertaken. Some 100 (73.5%) participants received the intended randomised arthroscopic surgical management, although only 63 (46.3%) received an arthroscopic repair.

Of the 137 participants randomised to receive open surgical management, 85 (62.0%) underwent an open repair of a tear and five (3.6%) an arthroscopic repair (see *Table 10*). Some 24 participants underwent an arthroscopic procedure and, as with the participants randomised to arthroscopic management, the most common procedure was a shoulder subacromial decompression. Twenty-three participants withdrew from any surgery. The principal reasons for participants withdrawing from surgery were related to medical conditions (primarily cardiac events) or participants being asymptomatic and not judged to be associated with either of the allocated procedures.

Non-randomised population

Similar proportions of non-randomised participants as randomised participants received the various management strategies, suggesting that the participants were broadly similar and their management was not biased by the surgeons' preferred techniques.

TABLE 10 Surgical management

Surgical management	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Received an arthroscopic repair	63 (46.3)	5 (3.6)	50 (54.9)	2 (2.4)
Received a converted arthroscopic procedure	9 (6.6)		1 (1.1)	
Received an open repair		85 (62.0)		40 (48.8)
Received an arthroscopic procedure	28 (20.6)	24 (17.5)	23 (25.3)	26 (31.7)
Details of procedure				
SAD	20 (14.7)	16 (11.7)	14 (15.4)	18 (22.0)
SAD and ACJ resection	1 (0.7)	3 (2.2)	4 (4.4)	6 (7.3)
Biceps tenotomy	2 (1.5)		1 (1.1)	
Capsular release	1 (0.7)	2 (1.5)		1 (1.2)
PTT repair		1 (0.7)		
Partial repair		1 (0.7)		
Type of procedure not documented	4 (3.0)	1 (0.7)	4 (4.4)	1 (1.2)
Withdrawn from intervention	36 (26.5)	23 (16.8)	15 (16.5)	12 (14.6)
Awaiting surgery when study ended	2 (1.5)	2 (1.5)	2 (2.2)	
Cancelled because of other surgery		2 (1.5)	1 (1.1)	
Complete withdrawal from study	2 (1.5)			
Family commitments	2 (1.5)	1 (0.7)		
No surgery on medical grounds	11 (8.1)	1 (0.7)	3 (3.3)	2 (2.4)
Patient asymptomatic	7 (5.1)	7 (5.1)	2 (2.2)	5 (6.1)
Patient deceased	1 (0.7)			
Patient did not want surgery	3 (2.2)	2 (1.5)	3 (3.3)	2 (2.4)
Patient not happy with hospital			1 (1.1)	
Patient withdrew from NHS waiting list	4 (2.9)	5 (3.6)		1 (1.2)
Personal reasons				2 (2.4)
Shoulder problem improved without surgery			1 (1.1)	
Unknown	1 (0.7)	1 (0.7)	2 (2.2)	
Work commitments	3 (2.2)	2 (1.5)		
Surgery type missing			2 (2.2)	2 (2.4)

ACJ, acromioclavicular joint; PTT, partial-thickness tear.

Operative details

Procedural details are shown in *Table 11* for those participants who received any surgery. The size of tear and surgical completeness were similar between the randomised groups. In the randomised group the ease of repair, although broadly similar, was reported to be easier for the open procedure (18% of arthroscopic operations were easy vs. 36% of open repairs). Such a difference was not observed in the non-randomised groups and therefore any difference must be interpreted with caution. However, the difference may be a proxy measure that the surgeons in the randomised comparison were more comfortable with the open than the arthroscopic approach.

TABLE 11 Operative details

	Randomised, *n* (%)		Non-randomised, *n* (%)	
Operative detail	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Did not receive intervention	36 (26.5)	23 (16.8)	17 (18.7)	14 (17.1)
Received allocated repair	63 (46.3)	85 (62.0)	50 (54.9)	40 (48.8)
Received allocated procedure	100 (73.5)	85 (62.0)	74 (81.3)	40 (48.8)
Received any surgery	100 (73.5)	114 (83.2)	74 (81.3)	68 (82.9)
Procedure side				
Left	40 (40.0)	33 (28.9)	22 (29.7)	27 (39.7)
Right	59 (59.0)	80 (70.2)	51 (68.9)	41 (60.3)
Missing	1 (1.0)	1 (0.9)	1 (1.4)	
Ease of repair				
Easy	18 (18.0)	41 (36.0)	13 (17.6)	11 (16.2)
Moderate	28 (28.0)	27 (23.7)	19 (25.7)	14 (20.6)
Difficult	17 (17.0)	12 (10.5)	11 (14.9)	11 (16.2)
Impossible	7 (7.0)	9 (7.9)	8 (10.8)	8 (11.8)
Missing	30 (30.0)	25 (21.9)	23 (31.1)	24 (35.3)
Size of tear				
Small	23 (23.0)	26 (22.8)	11 (14.9)	7 (10.3)
Medium	27 (27.0)	36 (31.6)	10 (13.5)	12 (17.6)
Large	13 (13.0)	19 (16.7)	18 (24.3)	13 (19.1)
Massive	15 (15.0)	13 (11.4)	18 (24.3)	16 (23.5)
Not a tear	21 (21.0)	16 (14.0)	15 (20.3)	20 (29.4)
Missing	1 (1.0)	4 (3.5)	2 (2.7)	
Surgical opinion of completeness of repair				
Poor	8 (8.0)	7 (6.1)	4 (5.4)	6 (8.8)
Good	41 (41.0)	46 (40.4)	29 (39.2)	22 (32.4)
Excellent	16 (16.0)	35 (30.7)	9 (12.2)	11 (16.2)
Missing	35 (35.0)	26 (22.8)	32 (43.2)	29 (42.6)
Total time in theatre (minutes), *n*, mean (SD)	73, 100.3 (42.0)	96, 87.6 (28.9)	46, 86.8 (32.5)	49, 85.9 (46.7)
Operation time (minutes), *n*, mean (SD)	72, 69.4 (36.7)	89, 57.2 (21.9)	36, 57.3 (27.2)	39, 63.3 (36.0)

The operation time is also shown in *Table 11*. For the randomised trial, the mean operation time in minutes was statistically significantly lower in the open procedure group (–12.2, 95% CI –21.4 to –3.0; $p = 0.010$) as was the mean total time in minutes in theatre (–12.7, 95% CI –23.5 to –1.9; $p = 0.021$). In the non-randomised groups, the times were similar.

Intraoperative complications

Table 12 shows the intraoperative complications. The number of events was generally low. There were 11 (8.1%) participants with any intraoperative complication in the randomised arthroscopic group compared with nine (6.6%) in the randomised open group. The difference was not statistically significant (difference 3.1%, 95% CI –4.8% to 11.0%; $p = 0.190$). The event rates in the non-randomised population were similar to those in the randomised population. There were no perioperative deaths.

Adverse events and deaths

Three participants in the randomised arthroscopic group and three in the randomised open group required inpatient hospitalisation as a result of taking part in the UKUFF trial. The inpatient admissions were as a result of two participants in each group requiring revision surgery and a single participant in each group having a postoperative complication. The first complication involved a participant with a deep infection, which required formal debridement and vacuum pump application. He had this surgery after 3 weeks of treatment by his GP with antibiotics. The second complication involved a participant requiring a longer stay in hospital following a continuous interscalene block in the shoulder for postoperative pain relief and some bleeding during surgery. There was a single case of revision surgery in each of the non-randomised groups. All complications and revision surgeries were managed within 17 months of randomisation.

Seven participants died while in follow-up ($n = 3$ randomised arthroscopic; $n = 1$ randomised open; $n = 3$ non-randomised arthroscopic; $n = 1$ non-randomised open). Two participants died of cancer, two were involved in road traffic accidents, one died of an unrelated and undisclosed illness and two had an unknown cause of death.

TABLE 12 Intraoperative complications

	Randomised, *n* (%)		Non-randomised, *n* (%)	
Complication	Arthroscopic ($n = 136$)	Open ($n = 137$)	Arthroscopic ($n = 91$)	Open ($n = 82$)
Intraoperative problem				
Anaesthetic	1 (1.0)	1 (0.9)	1 (1.4)	1 (1.5)
Equipment	3 (3.0)	1 (0.9)	2 (2.7)	2 (2.9)
Implant		1 (0.9)	1 (1.4)	1 (1.5)
Surgical	9 (9.0)	2 (1.8)	4 (5.4)	2 (2.9)
Other	5 (5.0)	6 (5.3)	7 (9.5)	10 (14.7)
Staff problems				2 (2.9)
Any intraoperative problem	11 (8.1)	9 (6.6)	14 (15.4)	11 (13.4)
Did the procedure change as a result of an intraoperative problem?				
Yes	4 (36.4)	3 (33.3)	9 (64.3)	6 (54.5)
No	7 (63.6)	4 (44.4)	4 (28.6)	3 (27.3)
Unsure			1 (7.1)	
Missing		2 (22.2)		2 (18.2)

Two-week follow-up

Follow-up measures timed to occur at 2 weeks post surgery are shown in *Table 13*. Very few participants reported being pain free and approximately two-thirds were taking painkillers. Of those participants who were employed, about 80% were still off sick. There were no clinically important differences between or within any of the randomised or non-randomised groups.

TABLE 13 Two-week follow-up

Question	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Completed follow-up forms	94 (69.1)	112 (81.8)	70 (76.9)	71 (86.6)
Within the last 24 hours, have you been wearing a sling at all?				
Yes	60 (63.8)	78 (69.6)	44 (62.9)	47 (66.2)
No	32 (34.0)	31 (27.7)	26 (37.1)	21 (29.6)
Missing	2 (2.1)	3 (2.7)		3 (4.2)
If yes, how long have you worn the sling for?				
> 12 hours	52 (86.7)	71 (91.0)	39 (88.6)	30 (63.8)
Between 6 and 12 hours	4 (6.7)	5 (6.4)	1 (2.3)	9 (19.1)
> 3 hours but < 6 hours	4 (6.7)	1 (1.3)	2 (4.5)	5 (10.6)
< 3 hours		1 (1.3)		1 (2.1)
Missing			2 (4.5)	2 (4.3)
Within the last 24 hours, how would you describe the worst pain from your shoulder?				
None	6 (6.4)	6 (5.4)	5 (7.1)	7 (9.9)
Mild	30 (31.9)	34 (30.4)	25 (35.7)	18 (25.4)
Moderate	36 (38.3)	50 (44.6)	23 (32.9)	33 (46.5)
Severe	17 (18.1)	19 (17.0)	12 (17.1)	9 (12.7)
Unbearable	3 (3.2)	1 (0.9)	5 (7.1)	1 (1.4)
Missing	2 (2.1)	2 (1.8)		3 (4.2)
Within the last 24 hours, how much has pain from your shoulder interfered with your usual work?				
Not at all	17 (18.1)	18 (16.1)	22 (31.4)	16 (22.5)
A little bit	16 (17.0)	10 (8.9)	14 (20.0)	10 (14.1)
Moderately	24 (25.5)	43 (38.4)	11 (15.7)	18 (25.4)
Greatly	24 (25.5)	25 (22.3)	9 (12.9)	17 (23.9)
Totally	11 (11.7)	13 (11.6)	14 (20.0)	7 (9.9)
Missing	2 (2.1)	3 (2.7)		3 (4.2)

continued

TABLE 13 Two-week follow-up (*continued*)

Question	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Were you troubled by pain from your shoulder in bed last night?				
No, not at all	25 (26.6)	25 (22.3)	17 (24.3)	19 (26.8)
Yes, just at first	8 (8.5)	6 (5.4)	4 (5.7)	5 (7.0)
Yes, during some of the night	38 (40.4)	44 (39.3)	32 (45.7)	27 (38.0)
Yes, throughout the night	21 (22.3)	35 (31.3)	17 (24.3)	17 (23.9)
Missing	2 (2.1)	2 (1.8)		3 (4.2)
Within the last 24 hours, have you taken any painkillers because of your shoulder?				
Yes	62 (66.0)	76 (67.9)	45 (64.3)	49 (69.0)
No	29 (30.9)	34 (30.4)	25 (35.7)	19 (26.8)
Missing	3 (3.2)	2 (1.8)		3 (4.2)
If yes, how many painkillers have you taken in the last 24 hours?				
1	29 (46.8)	38 (50.0)	23 (51.1)	25 (51.0)
2	23 (37.1)	30 (39.5)	16 (35.6)	15 (30.6)
3	7 (11.3)	5 (6.6)	6 (13.3)	6 (12.2)
4	1 (1.6)	1 (1.3)		2 (4.1)
5	1 (1.6)	1 (1.3)		1 (2.0)
Missing	1 (1.6)	1 (1.3)		
During the (last 2 weeks) time since the completion of surgery or rest then exercise, have you received any additional treatment on your shoulder?				
Yes	3 (3.2)	17 (15.2)	8 (11.4)	3 (4.2)
No	84 (89.4)	87 (77.7)	59 (84.3)	56 (78.9)
Missing	7 (7.4)	8 (7.1)	3 (4.3)	12 (16.9)
If yes, what was the additional treatment?				
Injection			1 (12.5)	
Antibiotics		1 (5.9)		
Physiotherapy	1 (33.3)	4 (23.5)	4 (50.0)	1 (33.3)
Wound or dressing		5 (29.4)	2 (25.0)	1 (33.3)
Not shoulder	1 (33.3)	2 (11.8)		1 (33.3)
Pain relief	1 (33.3)	5 (29.4)	1 (12.5)	
Are you currently employed?				
Yes	46 (48.9)	57 (50.9)	31 (44.3)	38 (53.5)
No	46 (48.9)	53 (47.3)	39 (55.7)	30 (42.3)
Missing	2 (2.1)	2 (1.8)		3 (4.2)
Are you currently off sick or working reduced duties?				
Yes, off sick	38 (82.6)	44 (77.2)	23 (74.2)	26 (68.4)
Yes, working reduced duties	3 (6.5)	5 (8.8)	3 (9.7)	4 (10.5)
No, working usual hours or duties	5 (10.9)	8 (14.0)	4 (12.9)	6 (15.8)
Missing			1 (3.2)	2 (5.3)

Eight-week follow-up

Follow-up measures timed to occur at 8 weeks post surgery are shown in *Table 14*. The results were similar to those at the 2-week follow-up with the exception that the percentage reporting no or mild pain improved from 35% to 50% with an apparent concomitant effect of reducing painkiller use from 66% to 55% and increasing the number of participants returning to usual work (no or a little interference) from 28% to 55%. There were no clinically important differences between or within any of the randomised or non-randomised groups.

TABLE 14 Eight-week follow-up

Question	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Completed follow-up forms	97 (71.3)	113 (82.5)	70 (76.9)	58 (70.7)
Within the last 24 hours, have you been wearing a sling at all?				
Yes	6 (6.2)	14 (12.4)	6 (8.6)	7 (12.1)
No	91 (93.8)	99 (87.6)	64 (91.4)	51 (87.9)
If yes, how long have you worn the sling for?				
> 12 hours	1 (16.7)	3 (21.4)	3 (50.0)	1 (14.3)
Between 6 and 12 hours	1 (16.7)	4 (28.6)		1 (14.3)
> 3 hours but < 6 hours	1 (16.7)	7 (50.0)	1 (16.7)	1 (14.3)
< 3 hours	3 (50.0)		2 (33.3)	2 (28.6)
Missing				2 (28.6)
Within the last 24 hours, how would you describe the worst pain you have had from your shoulder?				
None	11 (11.3)	12 (10.6)	8 (11.4)	7 (12.1)
Mild	38 (39.2)	50 (44.2)	22 (31.4)	24 (41.4)
Moderate	33 (34.0)	29 (25.7)	21 (30.0)	20 (34.5)
Severe	14 (14.4)	20 (17.7)	15 (21.4)	7 (12.1)
Unbearable	1 (1.0)	1 (0.9)	4 (5.7)	
Missing		1 (0.9)		
Within the last 24 hours, how much has pain from your shoulder interfered with your usual work?				
Not at all	31 (32.0)	26 (23.0)	20 (28.6)	18 (31.0)
A little bit	23 (23.7)	35 (31.0)	20 (28.6)	15 (25.9)
Moderately	32 (33.0)	37 (32.7)	14 (20.0)	18 (31.0)
Greatly	9 (9.3)	12 (10.6)	11 (15.7)	6 (10.3)
Totally	2 (2.1)	3 (2.7)	5 (7.1)	1 (1.7)
Were you troubled by pain from your shoulder in bed last night?				
No, not at all	37 (38.1)	40 (35.4)	25 (35.7)	23 (39.7)
Yes, just at first	8 (8.2)	9 (8.0)	4 (5.7)	2 (3.4)
Yes, during some of the night	35 (36.1)	38 (33.6)	23 (32.9)	21 (36.2)
Yes, throughout the night	17 (17.5)	26 (23.0)	18 (25.7)	12 (20.7)

continued

TABLE 14 Eight-week follow-up (*continued*)

Question	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Within the last 24 hours, have you taken any painkillers for your shoulder?				
Yes	44 (45.4)	59 (52.2)	36 (51.4)	32 (55.2)
No	53 (54.6)	54 (47.8)	34 (48.6)	26 (44.8)
If yes, how many painkillers have you taken?				
1	25 (56.8)	34 (57.6)	17 (47.2)	15 (46.9)
2	13 (29.5)	19 (32.2)	9 (25.0)	8 (25.0)
3	4 (9.1)	3 (5.1)	4 (11.1)	1 (3.1)
4	1 (2.3)			1 (3.1)
Missing	1 (2.3)	3 (5.1)	6 (16.7)	7 (21.9)
During the time (last 6 weeks) since we spoke to you last, have you had any additional treatment for your shoulder?				
Yes	7 (7.2)	10 (8.8)	5 (7.1)	7 (12.1)
No	85 (87.6)	100 (88.5)	63 (90.0)	49 (84.5)
Missing	5 (5.2)	3 (2.7)	2 (2.9)	2 (3.4)
If yes, what additional treatment did you receive?				
Injection		1 (10.0)		
Surgery			1 (20.0)	
Antibiotics		2 (20.0)		1 (14.3)
Physiotherapy	7 (100.0)	4 (40.0)	2 (40.0)	6 (85.7)
Wound or dressing		1 (10.0)		
Pain relief				
Hospital admission			1 (20.0)	
Surgery and antibiotics		2 (20.0)		
Injection and antibiotics			1 (20.0)	
Are you currently employed?				
Yes	47 (48.5)	60 (53.1)	26 (37.1)	26 (44.8)
No	50 (51.5)	52 (46.0)	41 (58.6)	28 (48.3)
Missing		1 (0.9)	3 (4.3)	4 (6.9)
Are you currently off sick or working reduced hours?				
Yes, off sick	23 (48.9)	29 (48.3)	13 (50.0)	14 (53.8)
Yes, working reduced duties	9 (19.1)	12 (20.0)	4 (15.4)	4 (15.4)
No, working usual hours/duties	15 (31.9)	18 (30.0)	9 (34.6)	8 (30.8)
Missing		1 (1.7)		

Outcomes at 8, 12 and 24 months

Outcomes at 8, 12 and 24 months were primarily obtained from questionnaire returns. As described in *Chapter 3* and reiterated here in *Table 15*, the return rates were similar across groups and ranged from 90% at 8 and 12 months to 86% at 24 months. There were no notable differences in baseline characteristics between those who had completed a questionnaire at 24 months and those who had not (*Table 16*). The only exception to this was a statistically significant difference in housing status, with 84.7% of homeowners in the responder group compared with 71.1% in the non-responder group. Given the possibility of multiple statistical testing, the difference should be interpreted with caution. As described in *Chapter 2*, these results confirmed that a repeated measures analysis assuming no differential loss to follow-up could be considered.

Health status

Health status measures at 8, 12 and 24 months are shown in *Table 17*. Full details of the statistical testing of the health status measures can be found in the following sections.

TABLE 15 Questionnaire response rates at 8, 12 and 24 months

	Randomised, *n* (%)		Non-randomised, *n* (%)	
Time point (months)	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
8	121 (89.0)	127 (92.7)	85 (93.4)	75 (91.5)
12	123 (90.4)	123 (89.8)	84 (92.3)	76 (92.7)
24	117 (86.0)	118 (86.1)	79 (86.8)	75 (91.5)

TABLE 16 Baseline characteristics of responders and non-responders at 24 months

Characteristic	Responder, *n* (%)	Non-responder, *n* (%)	*p*-value (two-sided)
Age (years), *n*, mean (SD)	235, 62.8 (7.0)	38, 63.1 (9.1)	0.824
Years with shoulder problem, *n*, mean (SD)	235, 2.4 (4.0)	38, 3.1 (8.0)	0.404
OSS, *n*, mean (SD)	235, 25.9 (7.9)	38, 24.0 (8.5)	0.165
SPADI, *n*, mean (SD)	234, 60.3 (21.8)	38, 67.3 (22.3)	0.068
SPADI pain, *n*, mean (SD)	235, 69.3 (19.8)	38, 74.9 (20.6)	0.109
SPADI disability, *n*, mean (SD)	233, 54.7 (24.7)	38, 62.5 (24.9)	0.072
MHI-5, *n*, mean (SD)	235, 22.7 (4.7)	38, 22.9 (4.6)	0.771
EQ-5D, *n*, mean (SD)	233, 0.543 (0.290)	38, 0.472 (0.319)	0.170
Sex			
Male	144 (61.3)	25 (65.8)	0.595
Female	91 (38.7)	13 (34.2)	
Handedness			
Right-handed	210 (89.4)	30 (78.9)	0.184
Left-handed	18 (7.7)	6 (15.8)	
Both	7 (3.0)	2 (5.3)	

continued

TABLE 16 Baseline characteristics of responders and non-responders at 24 months (*continued*)

Characteristic	Responder, *n* (%)	Non-responder, *n* (%)	*p*-value (two-sided)
Highest qualification			
None	101 (43.0)	21 (55.3)	0.207
Secondary	80 (34.0)	10 (26.3)	
Higher	53 (22.6)	6 (15.8)	
Missing	1 (0.4)	1 (2.6)	
Housing tenure			
Home owner	199 (84.7)	27 (71.1)	0.020
Private rent	6 (2.6)	2 (5.3)	
Council rent	19 (8.1)	7 (18.4)	
Other	11 (4.7)	1 (2.6)	
Missing		1 (2.6)	
Lives alone			
Yes	27 (11.5)	8 (21.1)	0.253
No	191 (81.3)	28 (73.7)	
Missing	17 (7.2)	2 (5.3)	
Employment status			
Full-time	89 (37.9)	16 (42.1)	0.567
Part-time	31 (13.2)	2 (5.3)	
Homemaker	8 (3.4)	1 (2.6)	
Retired	97 (41.3)	16 (42.1)	
Unemployed	8 (3.4)	3 (7.9)	
Missing	2 (0.9)		
Type of work			
Manual	67 (55.8)	10 (55.6)	0.474
Non-manual	48 (40.0)	6 (33.3)	
Not sure	4 (3.3)	2 (11.1)	
Missing	1 (0.8)		
Off sick or working reduced duties			
Yes, off sick	13 (10.8)		0.096
Yes, reduced duties	12 (10.0)	5 (27.8)	
No, working usual hours	91 (75.8)	12 (66.7)	
Missing	4 (3.3)	1 (5.6)	
Able to do job			
No	127 (54.0)	19 (50.0)	0.443
Yes, but with difficulty	104 (44.3)	17 (44.7)	
Yes, with no difficulty	3 (1.3)	1 (2.6)	
Missing	1 (0.4)	1 (2.6)	

TABLE 17 Health status at 8, 12 and 24 months

Measure	Randomised, *n*, mean (SD)		Effect size	95% CI	*p*-value	Non-randomised, *n*, mean (SD)	
	Arthroscopic	Open				Arthroscopic	Open
OSS							
Baseline	129, 26.3 (8.2)	131, 25.0 (8.0)				91, 25.3 (8.9)	82, 25.9 (8.4)
8 months	121, 36.1 (9.2)	127, 37.0 (8.6)	–1.27	–3.21 to 0.67	0.200	85, 37.2 (9.7)	75, 37.4 (9.2)
12 months	122, 38.3 (9.5)	122, 39.6 (8.5)	–1.60	–3.55 to 0.35	0.108	83, 37.4 (10.3)	75, 40.6 (6.8)
24 months (primary outcome)	114, 41.7 (7.9)	115, 41.5 (7.9)	–0.76	–2.75 to 1.22	0.452	78, 41.3 (7.7)	75, 41.3 (7.3)
SPADI							
Baseline	128, 60.4 (22.1)	130, 61.8 (21.7)				91, 60.6 (23.1)	82, 60.7 (20.1)
8 months	117, 31.8 (26.6)	124, 31.7 (27.8)	1.02	–4.73 to 6.77	0.728	82, 28.7 (24.9)	73, 27.8 (23.3)
12 months	119, 24.2 (26.3)	120, 23.4 (26.4)	1.83	–3.93 to 7.59	0.533	80, 23.9 (25.8)	74, 18.6 (20.2)
24 months	115, 16.1 (21.7)	118, 17.5 (23.7)	0.50	–5.30 to 6.30	0.866	75, 16.6 (21.8)	71, 17.3 (22.9)
SPADI pain							
Baseline	128, 69.2 (19.6)	130, 70.5 (20.4)				91, 70.0 (21.8)	82, 69.6 (19.5)
8 months	118, 36.7 (27.7)	126, 35.4 (28.9)	2.00	–4.26 to 8.26	0.532	84, 32.9 (27.8)	72, 31.7 (24.9)
12 months	119, 28.1 (27.8)	119, 25.9 (27.1)	2.91	–3.39 to 9.21	0.365	80, 26.2 (27.0)	75, 23.1 (23.8)
24 months	114, 18.7 (23.1)	118, 20.1 (26.1)	0.92	–5.42 to 7.26	0.777	75, 18.0 (22.8)	71, 20.3 (24.5)
SPADI disability							
Baseline	128, 54.9 (25.1)	130, 56.5 (24.4)				91, 54.7 (25.9)	82, 55.2 (21.9)
8 months	117, 28.7 (26.9)	124, 29.3 (28.1)	0.41	–5.26 to 6.07	0.889	82, 26.3 (24.4)	74, 26.2 (24.9)
12 months	119, 21.8 (26.3)	120, 21.7 (26.9)	1.12	–4.57 to 6.80	0.700	80, 22.4 (26.9)	74, 16.2 (19.5)
24 months	116, 14.8 (22.5)	118, 15.8 (22.8)	0.36	–5.35 to 6.07	0.902	76, 16.3 (22.7)	72, 15.5 (22.5)

continued

TABLE 17 Health status at 8, 12 and 24 months (*continued*)

	Randomised, *n*, mean (SD)					Non-randomised, *n*, mean (SD)	
Measure	Arthroscopic	Open	Effect size	95% CI	*p*-value	Arthroscopic	Open
MHI-5							
Baseline	128, 22.4 (4.9)	130, 22.9 (4.5)				90, 22.4 (5.1)	82, 22.1 (4.7)
8 months	118, 23.8 (4.9)	124, 23.8 (4.4)	0.32	–0.61 to 1.26	0.500	81, 23.8 (4.6)	74, 24.0 (4.1)
12 months	118, 23.5 (5.0)	119, 23.6 (4.6)	0.13	–0.81 to 1.07	0.783	78, 24.4 (4.6)	73, 24.2 (3.8)
24 months	116, 24.4 (4.0)	118, 24.3 (4.5)	0.22	–0.72 to 1.17	0.648	76, 23.8 (4.9)	71, 24.2 (4.2)
EQ-5D							
Baseline	129, 0.551 (0.297)	131, 0.518 (0.293)				91, 0.514 (0.326)	81, 0.536 (0.287)
8 months	120, 0.680 (0.300)	124, 0.700 (0.257)	–0.032	–0.092 to 0.028	0.296	79, 0.709 (0.244)	74, 0.711 (0.194)
12 months	119, 0.727 (0.278)	118, 0.711 (0.300)	0.011	–0.050 to 0.071	0.724	80, 0.696 (0.293)	71, 0.761 (0.192)
24 months	116, 0.760 (0.235)	118, 0.778 (0.219)	–0.043	–0.104 to 0.017	0.163	79, 0.760 (0.262)	74, 0.753 (0.258)

Oxford Shoulder Score

Figure 2 graphically displays the OSS over the course of the follow-up period for the randomised and non-randomised groups. All groups followed a similar pattern. The OSS increased markedly from baseline (mean 25.7) to 8 months (mean 36.5) and continued to increase thereafter (at a much slower rate) to 24 months (mean 41.5).

European Quality of Life-5 Dimensions

Figure 3 displays the EQ-5D score over the follow-up period. The pattern is similar to that seen for the OSS.

Shoulder Pain and Disability Index

The SPADI overall score, together with the pain and disability subscales (*Figures 4–6*), followed a similar pattern to that for the OSS (note that a lower SPADI score is a better outcome), with a large improvement from baseline at 8 months followed by a smaller rate of improvement thereafter. All randomised and non-randomised groups followed a similar pattern.

Mental Health Inventory

The MHI-5 scores showed very little change across time from baseline (*Figure 7*).

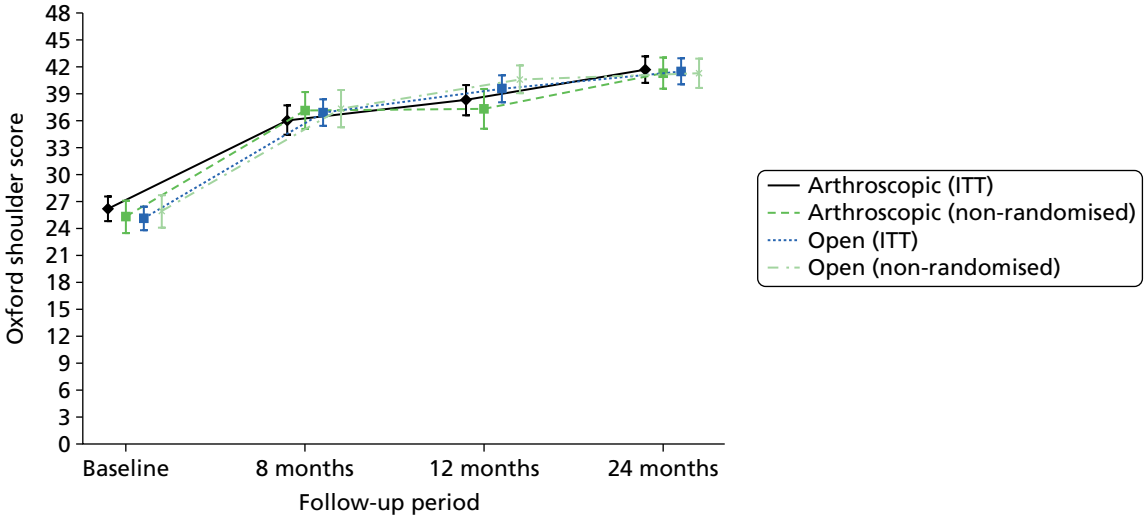

FIGURE 2 Means and 95% CIs for the OSS across time for the ITT and non-randomised groups.

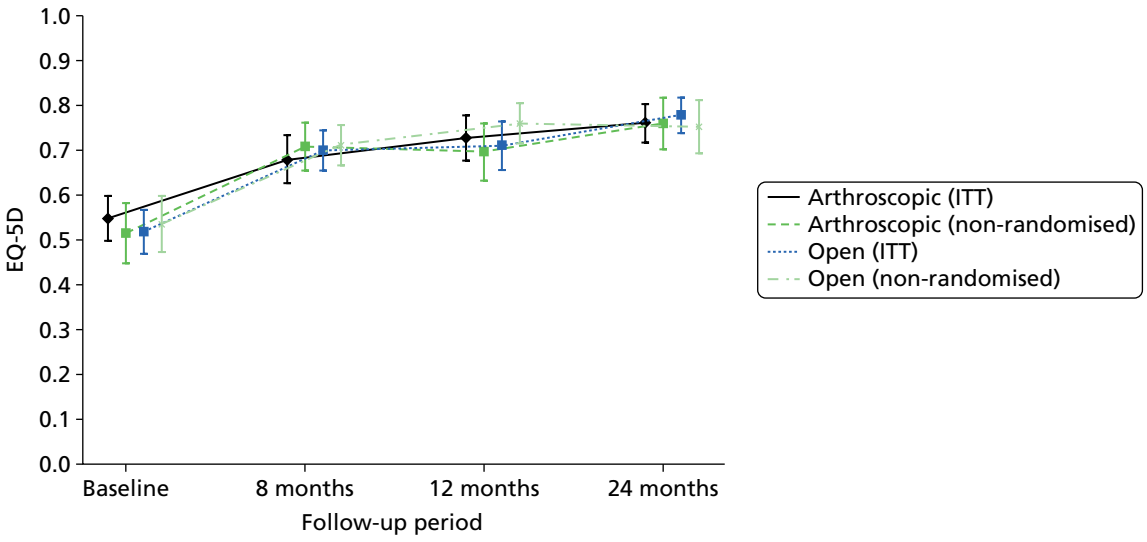

FIGURE 3 Means and 95% CIs for the EQ-5D across time for the ITT and non-randomised groups.

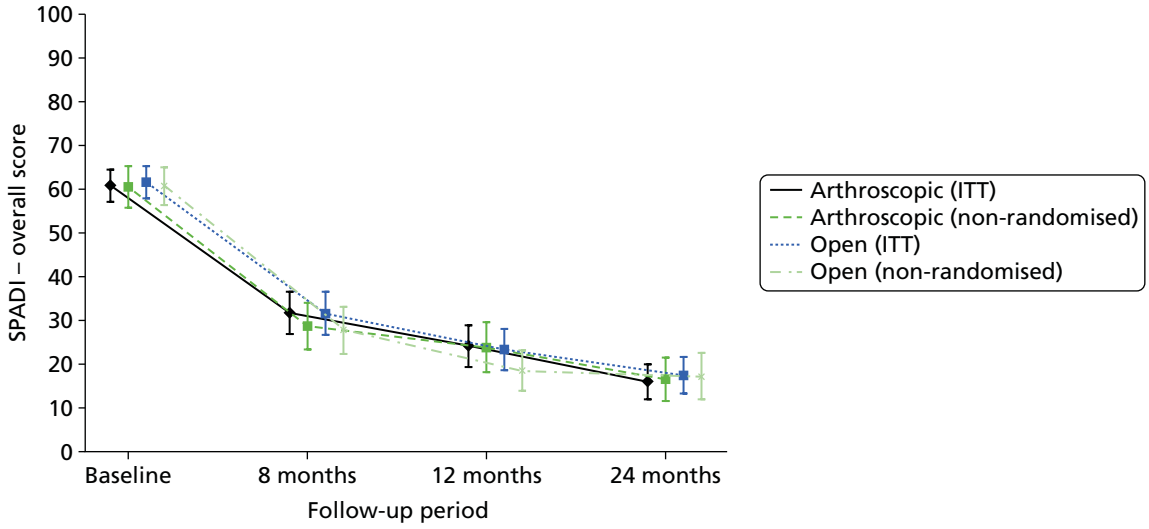

FIGURE 4 Means and 95% CIs for the SPADI overall score across time for the ITT and non-randomised groups.

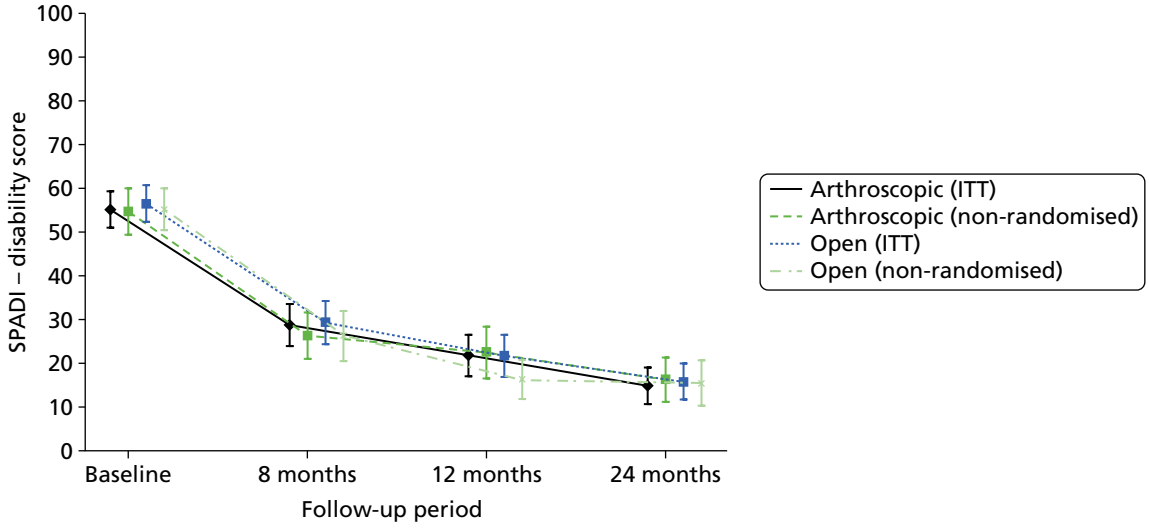

FIGURE 5 Means and 95% CIs for the SPADI disability subscale score across time for the ITT and non-randomised groups.

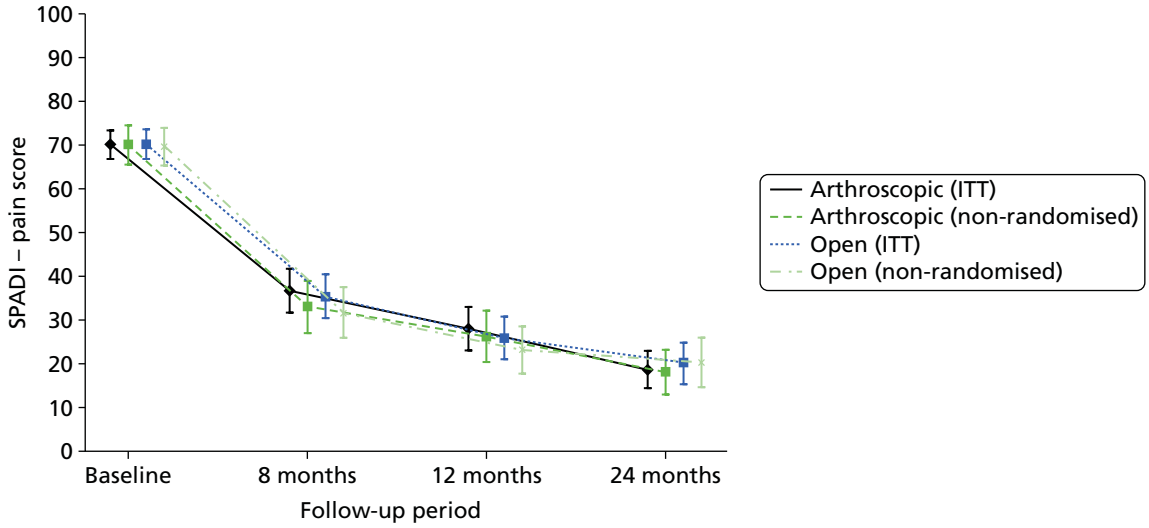

FIGURE 6 Means and 95% CIs for the SPADI pain subscale score across time for the ITT and non-randomised groups.

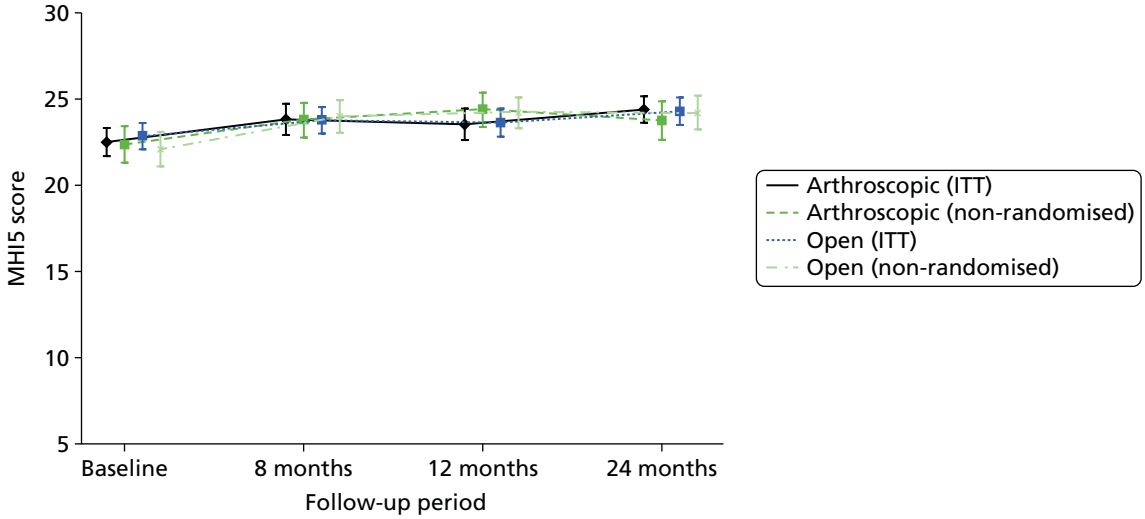

FIGURE 7 Means and 95% CIs for the MHI-5 score across time for the ITT and non-randomised groups.

Symptoms

A comparison of current shoulder problems with baseline levels is given in *Table 18*. In response to a transition item concerning change in their shoulder problems at 8 months, 77% of participants reported that shoulder problems were much or slightly better, increasing to 85% at 24 months. When asked how pleased they were with their shoulder symptoms, on average 77% of participants were either very or fairly pleased at 8 months, increasing to 83% by 24 months. All groups responded in a similar manner.

Employment information

Table 19 shows participant employment status at 8, 12 and 24 months. There was no substantial change in employment status from 8 to 24 months.

Magnetic resonance imaging findings at 12 months post surgery

The findings of those participants undergoing an MRI at 12 months post surgery are displayed in *Table 20*. Of the 136 participants randomised to receive arthroscopic repair, 69 (51%) had an MRI scan at 12 months. For the 137 participants randomised to receive open repair, 83 (61%) had an MRI. The primary reasons for not receiving were that the patient did not have a tear at initial surgery, it was impossible to repair or the patient received a revision surgery prior to 12 months.

The rate of re-tear was similar across the randomised groups (46.4% vs. 38.6% for arthroscopic and open surgery respectively) (relative effect: OR 1.52, 95% CI 0.84 to 2.75; absolute risk difference 9.5%, 95% CI –6.9% to 25.8%; $p = 0.256$).

TABLE 18 Change in symptoms and satisfaction ratings at 8, 12 and 24 months

Question	Randomised, *n* (%)					Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	OR	95% CI	*p*-value	Arthroscopic (*n* = 91)	Open (*n* = 82)
How are the problems related to your shoulder now compared with 8 months ago?							
Much better	63 (52.1)	76 (59.8)	0.80	0.41 to 1.58	0.522	55 (64.7)	47 (62.7)
Slightly better	30 (24.8)	22 (17.3)				14 (16.5)	17 (22.7)
No change	18 (14.9)	11 (8.7)				7 (8.2)	1 (1.3)
Slightly worse	3 (2.5)	6 (4.7)				4 (4.7)	4 (5.3)
Much worse	4 (3.3)	4 (3.1)				3 (3.5)	2 (2.7)
Missing	3 (2.5)	8 (6.3)				2 (2.4)	4 (5.3)
How are the problems related to your shoulder now compared with a year ago?							
Much better	72 (58.5)	85 (69.1)	0.57	0.31 to 1.03	0.061	51 (60.7)	56 (73.7)
Slightly better	20 (16.3)	18 (14.6)				19 (22.6)	11 (14.5)
No change	12 (9.8)	4 (3.3)				4 (4.8)	6 (7.9)
Slightly worse	9 (7.3)	5 (4.1)				1 (1.2)	1 (1.3)
Much worse	4 (3.3)	7 (5.7)				3 (3.6)	1 (1.3)
Missing	6 (4.9)	4 (3.3)				6 (7.1)	1 (1.3)
How are the problems related to your shoulder now compared with 2 years ago?							
Much better	83 (70.9)	81 (68.6)	0.97	0.43 to 2.18	0.939	61 (77.2)	49 (65.3)
Slightly better	16 (13.7)	20 (16.9)				6 (7.6)	14 (18.7)
No change	6 (5.1)	6 (5.1)				6 (7.6)	4 (5.3)
Slightly worse	5 (4.3)	4 (3.4)				3 (3.8)	3 (4.0)
Much worse	3 (2.6)	4 (3.4)				0 (0.0)	2 (2.7)
Missing	4 (3.4)	3 (2.5)				3 (3.8)	3 (4.0)
How pleased are you with your shoulder symptoms at 8 months?							
Very pleased	45 (37.2)	51 (40.2)	1.11	0.57 to 2.16	0.769	44 (51.8)	37 (49.3)
Fairly pleased	51 (42.1)	45 (35.4)				26 (30.6)	27 (36.0)
Not very pleased	17 (14.0)	18 (14.2)				6 (7.1)	5 (6.7)
Very disappointed	4 (3.3)	4 (3.1)				7 (8.2)	1 (1.3)
Missing	4 (3.3)	9 (7.1)				2 (2.4)	5 (6.7)
How pleased are you with your shoulder symptoms at 12 months?							
Very pleased	59 (48.0)	57 (46.3)	0.57	0.31 to 1.05	0.071	42 (50.0)	45 (59.2)
Fairly pleased	33 (26.8)	47 (38.2)				27 (32.1)	20 (26.3)
Not very pleased	16 (13.0)	8 (6.5)				8 (9.5)	6 (7.9)
Very disappointed	7 (5.7)	7 (5.7)				2 (2.4)	4 (5.3)
Missing	8 (6.5)	4 (3.3)				5 (6.0)	1 (1.3)
How pleased are you with your shoulder symptoms at 24 months?							
Very pleased	73 (62.4)	64 (54.2)	1.37	0.73 to 2.60	0.330	47 (59.5)	42 (56.0)
Fairly pleased	26 (22.2)	33 (28.0)				21 (26.6)	19 (25.3)
Not very pleased	7 (6.0)	13 (11.0)				7 (8.9)	7 (9.3)
Very disappointed	6 (5.1)	4 (3.4)				1 (1.3)	4 (5.3)
Missing	5 (4.3)	4 (3.4)				3 (3.8)	3 (4.0)

TABLE 19 Employment status at 8, 12 and 24 months

Employment status	Randomised, *n* (%)		Non-randomised, *n* (%)	
	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
Employed at 8 months				
Yes	51 (42.1)	54 (42.5)	29 (34.1)	33 (44.0)
No	67 (55.4)	63 (49.6)	54 (63.5)	38 (50.7)
Missing	3 (2.5)	10 (7.9)	2 (2.4)	4 (5.3)
Employed at 12 months				
Yes	50 (40.7)	49 (39.8)	23 (27.4)	32 (42.1)
No	68 (55.3)	70 (56.9)	56 (66.7)	43 (56.6)
Missing	5 (4.1)	4 (3.3)	5 (6.0)	1 (1.3)
Employed at 24 months				
Yes	42 (35.9)	42 (35.6)	22 (27.8)	31 (41.3)
No	71 (60.7)	72 (61.0)	54 (68.4)	41 (54.7)
Missing	4 (3.4)	4 (3.4)	3 (3.8)	3 (4.0)
If you are employed, are you off sick or working reduced duties because of your shoulder at 8 months?				
Yes, off sick	10 (8.3)	7 (5.5)	5 (5.9)	2 (2.7)
Yes, working reduced hours	4 (3.3)	8 (6.3)	4 (4.7)	7 (9.3)
No, working usual hours/duties	36 (29.8)	36 (28.3)	19 (22.4)	23 (30.7)
Missing	71 (58.7)	76 (59.8)	57 (67.1)	43 (57.3)
Are you currently out of work, off sick or working reduced duties because of your shoulder at 12 months?				
Yes	12 (9.8)	10 (8.1)	5 (6.0)	9 (11.8)
No	93 (75.6)	93 (75.6)	63 (75.0)	59 (77.6)
Missing	18 (14.6)	20 (16.3)	16 (19.0)	8 (10.5)
Are you currently out of work, off sick or working reduced duties because of your shoulder at 24 months?				
Yes	8 (6.8)	6 (5.1)	4 (5.1)	5 (6.7)
No	99 (84.6)	94 (79.7)	65 (82.3)	60 (80.0)
Missing	10 (8.5)	18 (15.3)	10 (12.7)	10 (13.3)

TABLE 20 Magnetic resonance imaging results

	Randomised, *n* (%)		Non-randomised, *n* (%)	
Measure	Arthroscopic (*n* = 136)	Open (*n* = 137)	Arthroscopic (*n* = 91)	Open (*n* = 82)
MRI scans received, *n*	69	83	41	40
Result of MRI scan				
Re-tear	32 (46.4)	32 (38.6)	15 (36.6)	14 (35.0)
No tear	32 (46.4)	47 (56.6)	23 (56.1)	24 (60.0)
Inconclusive	1 (1.4)	1 (1.2)		
Missing	4 (5.8)	3 (3.6)	3 (7.3)	2 (5.0)
Size of tear if MRI scan shows a re-tear				
Partial	2 (6.3)	1 (3.1)	1 (6.7)	
Small	9 (28.1)	10 (31.3)	1 (6.7)	4 (28.6)
Medium	5 (15.6)	9 (28.1)	6 (40.0)	5 (35.7)
Large	5 (15.6)	3 (9.4)	2 (13.3)	2 (14.3)
Massive	8 (25.0)	7 (21.9)	4 (26.7)	3 (21.4)
Missing	3 (9.4)	2 (6.3)	1 (6.7)	
OSS at 24 months, *n*, mean (SD)				
Re-tear	30, 41.8 (8.8)	29, 40.8 (7.6)	15, 38.8 (5.8)	13, 39.8 (7.2)
No tear	30, 44.5 (4.1)	47, 43.6 (5.8)	22, 43.9 (4.2)	20, 44.3 (4.5)
Impossible to repair	7, 37.3 (6.1)	8, 35.1 (9.7)	6, 37.0 (9.8)	8, 32.4 (9.8)

The OSS demonstrated a consistent pattern within each group, with the impossible-to-repair participants having the worst OSS, participants with a re-tear having a slightly better OSS and participants with no tear having the most improved OSS (see *Table 20*).

Per-protocol population

For completeness, data on the per-protocol population are included in *Appendix 1*. These data are from the 63 participants who were randomised to an arthroscopic procedure and who actually received an arthroscopic repair and the 85 participants who were randomised to an open procedure and who received an open repair. Similarly, the data reported also include the 50 arthroscopic repairs and the 40 open repairs in the non-randomised group.

Recognising that caution must be used when interpreting the per-protocol group, we nevertheless note that the lack of important differences between the arthroscopic and the open ITT groups was also observed in the per-protocol data. The similarity is illustrated visually in *Figures 8* and *9*, where the OSS and EQ-5D scores, respectively, are contrasted between the ITT population and the per-protocol population.

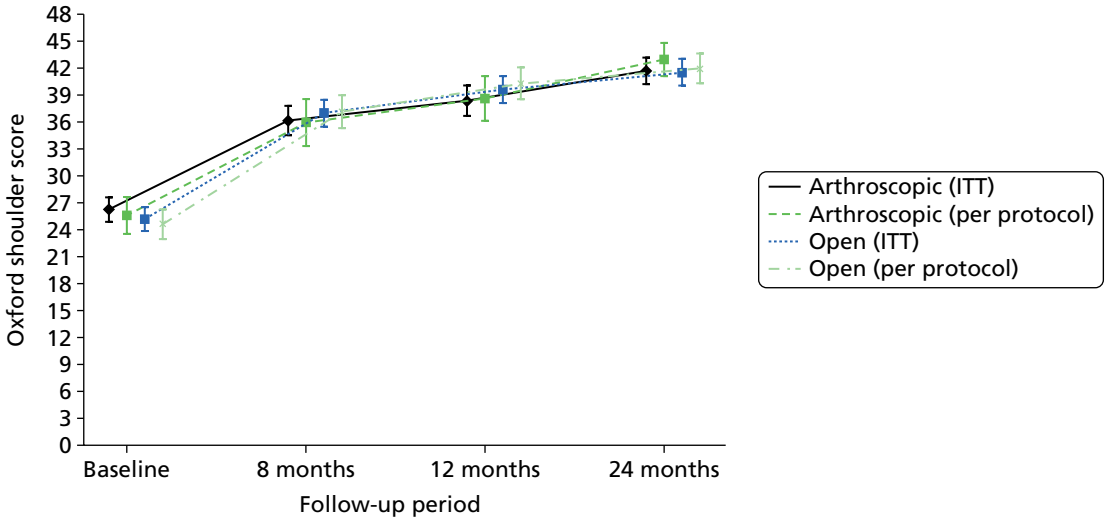

FIGURE 8 Means and 95% CIs for the OSS across time for the ITT and per-protocol groups.

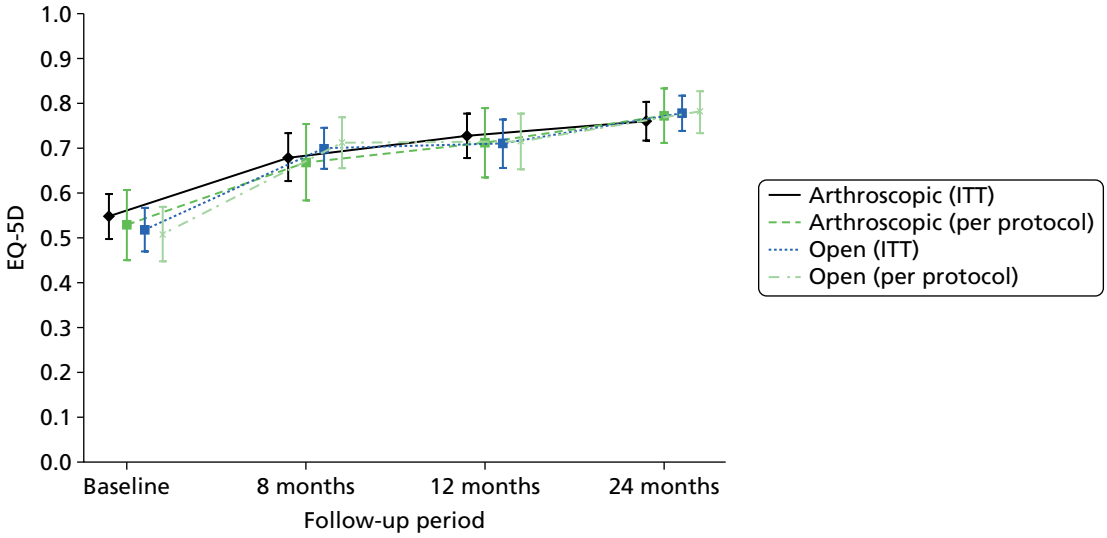

FIGURE 9 Means and 95% CIs for the EQ-5D across time for the ITT and per-protocol groups.

Statistical between-group analysis

Primary outcome

The pre-chosen primary outcome was the OSS score at 24 months' follow-up, for which the effect sizes and 95% CIs are shown in *Table 17*. Under ITT analysis there was no evidence of a difference between those randomised to receive an arthroscopic procedure and those randomised to receive an open procedure (difference –0.76, 95% CI –2.75 to 1.22; $p = 0.452$). The 95% CI was also small enough to exclude the prespecified clinically important difference of 3 points.

To test the sensitivity of the primary outcome to the actual procedure received we also performed a per-protocol analysis of the 24-month OSS using the instrumental variable approach described in *Chapter 2*. A similar result to that of the ITT analysis was produced, although the CIs were much wider, as expected (difference –0.46, 95% CI –5.30 to 4.39; $p = 0.854$). We are therefore confident that there was no evidence of important differences between surgical treatments.

Secondary outcomes

The secondary outcomes were the health status measures (EQ-5D, SPADI and MHI-5), the change in symptom measures (transition items regarding shoulder problems and shoulder symptoms) and satisfaction ratings ('How pleased are you with your shoulder symptoms?') at 8, 12 and 24 months, the OSS at 8 and 12 months and MRI-diagnosed re-tears at 12 months post surgery. Analyses of these outcomes are shown in *Tables 17* and *18*.

Health status

There was no evidence of any differences between the randomised groups for any of the health status measures at all follow-up times (see *Table 17*).

Change in symptoms and satisfaction

There was no evidence of any differences between the randomised groups for either of the symptom transition or satisfaction measures at all follow-up times (see *Table 18*). For example, at 24 months, when asked how pleased they were with their shoulder symptoms, 84.6% of participants in the arthroscopic group and 82.4% in the open group were either very or fairly pleased (OR 1.37, 95% CI 0.73 to 2.60; $p = 0.330$).

Magnetic resonance imaging findings

The rate of re-tear was similar across the randomised groups, at 46.4% in the arthroscopic repair group and 38.6% in the open surgery group (difference 9.5%, 95% CI –6.9% to 25.8%; $p = 0.256$).

Subgroup analysis

Two preplanned subgroup analyses on the primary outcome (OSS at 24 months) were conducted: size of tear at baseline assessment (small or medium vs. large or massive) and age at recruitment (< 65 years vs. ≥ 65 years). *Figure 10* displays the means and 95% CIs for the differences in OSS score at 24 months in the subgroups. There was no evidence that any of the subgroups was statistically significantly different at the 1% level ($p = 0.843$ for tear size and $p = 0.024$ for age).

Learning curve

The statistical model for investigating any trend in OSS at 24 months as surgeon experience increased during the trial did not demonstrate any significant learning effect (trend in OSS +0.04 per procedure, 95% CI –0.21 to 0.29; $p = 0.744$).

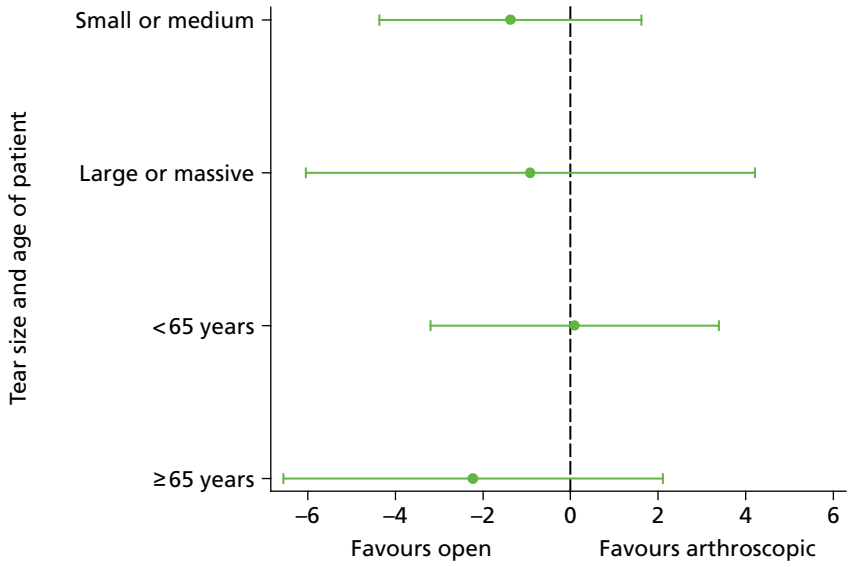

FIGURE 10 Prespecified subgroup analysis of the OSS at 24 months (size of tear; age of patient).

Chapter 5 Rest then exercise

In total, 214 patients were randomised to rest then exercise before the reconfiguration of the trial, with 44 randomised within stratum A (arthroscopic surgery vs. open surgery vs. rest then exercise), 90 within stratum B (arthroscopic surgery vs. rest then exercise) and 80 within stratum C (open surgery vs. rest then exercise). Data from these participants are presented in this chapter. Reflecting the observational status of these data, no statistical analysis or formal interpretation of the data is presented.

Description of the rest-then-exercise group at trial entry

All baseline data collected on these patients were presented in *Chapter 3*. We replicate a subset of the baseline data here to illustrate that participants randomised to rest then exercise across the three strata displayed broadly similar characteristics and beliefs at baseline (*Tables 21* and *22*, respectively).

TABLE 21 Participant characteristics of the rest-then-exercise groups at recruitment

Characteristic	Stratum A ($n = 44$), *n* (%)	Stratum B ($n = 90$), *n* (%)	Stratum C ($n = 80$), *n* (%)
Age (years)	44, 62.9 (7.5)	90, 64.7 (8.0)	80, 61.3 (6.8)
Years with shoulder problem	43, 2.0 (2.7)	87, 2.2 (3.3)	79, 2.3 (2.6)
Sex			
Male	28 (63.6)	63 (70.0)	51 (63.8)
Female	16 (36.4)	27 (30.0)	29 (36.3)
Handedness			
Right-handed	40 (90.9)	78 (86.7)	66 (82.5)
Left-handed	1 (2.3)	9 (10.0)	8 (10.0)
Both	2 (4.5)	3 (3.3)	5 (6.3)
Missing	1 (2.3)		1 (1.3)
Highest qualification			
None	23 (52.3)	37 (41.1)	25 (31.3)
Secondary	16 (36.4)	38 (42.2)	41 (51.3)
Higher	5 (11.4)	12 (13.3)	12 (15.0)
Missing		3 (3.3)	2 (2.5)

continued

TABLE 21 Participant characteristics of the rest-then-exercise groups at recruitment (*continued*)

Characteristic	Stratum A ($n = 44$), *n* (%)	Stratum B ($n = 90$), *n* (%)	Stratum C ($n = 80$), *n* (%)
Housing tenure			
Home owner	34 (77.3)	78 (86.7)	68 (85.0)
Private rent	3 (6.8)	2 (2.2)	4 (5.0)
Council rent	5 (11.4)	7 (7.8)	2 (2.5)
Other	2 (4.5)	2 (2.2)	5 (6.3)
Missing		1 (1.1)	1 (1.3)
Lives alone			
Yes	6 (13.6)	19 (21.1)	12 (15.0)
No	34 (77.3)	67 (74.4)	64 (80.0)
Missing	4 (9.1)	4 (4.4)	4 (5.0)
Employment status			
Full-time	12 (27.3)	30 (33.3)	35 (43.8)
Part-time	7 (15.9)	10 (11.1)	8 (10.0)
Homemaker	0 (0.0)	0 (0.0)	0 (0.0)
Retired	22 (50.0)	45 (50.0)	32 (40.0)
Unemployed	3 (6.8)	5 (5.6)	4 (5.0)
Missing			1 (1.3)
Type of work			
Manual	12 (63.2)	27 (67.5)	24 (55.8)
Non-manual	6 (31.6)	11 (27.5)	15 (34.9)
Not sure	1 (5.3)	1 (2.5)	3 (7.0)
Missing		1 (2.5)	1 (2.3)
Off sick or working reduced duties			
Yes, off sick	3 (15.8)	5 (12.5)	4 (9.3)
Yes, working reduced duties	5 (26.3)	8 (20.0)	8 (18.6)
No, working usual duties	11 (57.9)	27 (67.5)	31 (72.1)
Would you be able to do your job or everyday activities with arm in a sling?			
No	18 (40.9)	48 (53.3)	43 (53.8)
Yes, with difficulty	19 (43.2)	35 (38.9)	31 (38.8)
Yes, no difficulty	4 (9.1)	2 (2.2)	5 (6.3)
Missing	3 (6.8)	5 (5.6)	1 (1.3)

TABLE 22 Attitudes to surgery at recruitment in the rest-then-exercise groups

Attitude	Stratum A ($n = 44$), *n* (%)	Stratum B ($n = 90$), *n* (%)	Stratum C ($n = 80$), *n* (%)
Doctors rely on surgery too much			
Agree	3 (6.8)	5 (5.6)	5 (6.3)
Uncertain	26 (59.1)	35 (38.9)	29 (36.3)
Disagree	13 (29.5)	42 (46.7)	39 (48.8)
Strongly disagree	2 (4.5)	7 (7.8)	5 (6.3)
Missing		1 (1.1)	2 (2.5)
Doctors place too much trust in surgery			
Strongly agree	1 (2.3)		
Agree	9 (20.5)	7 (7.8)	8 (10.0)
Uncertain	22 (50.0)	35 (38.9)	33 (41.3)
Disagree	11 (25.0)	43 (47.8)	33 (41.3)
Strongly disagree	1 (2.3)	4 (4.4)	3 (3.8)
Missing		1 (1.1)	3 (3.8)
Worry about surgery risks			
Strongly agree	3 (6.8)	12 (13.3)	4 (5.0)
Agree	20 (45.5)	35 (38.9)	33 (41.3)
Uncertain	8 (18.2)	14 (15.6)	16 (20.0)
Disagree	12 (27.3)	23 (25.6)	20 (25.0)
Strongly disagree	1 (2.3)	4 (4.4)	4 (5.0)
Missing		2 (2.2)	3 (3.8)
Surgery should be only a last resort			
Strongly agree	6 (13.6)	12 (13.3)	11 (13.8)
Agree	17 (38.6)	48 (53.3)	36 (45.0)
Uncertain	9 (20.5)	12 (13.3)	13 (16.3)
Disagree	11 (25.0)	15 (16.7)	15 (18.8)
Strongly disagree	1 (2.3)	3 (3.3)	2 (2.5)
Missing			3 (3.8)

Outcomes in those allocated to rest then exercise

Outcomes of all those allocated to rest then exercise (i.e. by ITT) are presented in *Table 23*. As with the full trial data presented in previous chapters, these data show that participants demonstrated substantial improvements in quality of life from baseline to final follow-up at 2 years.

TABLE 23 Health status by ITT group

Measure	Stratum A (*n* = 44), *n*, mean (SD)	Stratum B (*n* = 90), *n*, mean (SD)	Stratum C (*n* = 80), *n*, mean (SD)
OSS			
Baseline	44, 23.7 (8.3)	90, 23.5 (8.0)	80, 26.2 (7.9)
8 months	39, 37.6 (7.0)	69, 34.8 (9.7)	68, 37.1 (8.8)
12 months	37, 39.3 (7.4)	65, 38.7 (8.9)	62, 40.1 (9.0)
24 months	34, 41.1 (7.5)	64, 39.2 (10.8)	56, 41.9 (8.2)
SPADI pain			
Baseline	44, 73.0 (22.0)	89, 73.1 (19.4)	80, 69.4 (18.2)
8 months	39, 33.3 (24.5)	68, 37.4 (28.1)	64, 30.0 (26.1)
12 months	35, 26.3 (27.1)	61, 24.3 (26.6)	58, 22.0 (25.2)
24 months	33, 19.1 (23.4)	62, 22.9 (30.1)	54, 16.4 (23.8)
SPADI disability			
Baseline	44, 63.0 (23.7)	90, 64.4 (22.1)	77, 57.7 (23.3)
8 months	38, 26.6 (23.5)	66, 33.3 (27.9)	65, 26.3 (25.3)
12 months	35, 21.8 (22.7)	60, 20.7 (24.7)	57, 20.0 (26.8)
24 months	32, 16.2 (22.4)	62, 20.0 (27.6)	54, 13.2 (22.3)
SPADI			
Baseline	44, 66.9 (22.1)	90, 67.8 (20.4)	79, 62.3 (20.1)
8 months	38, 29.2 (23.4)	67, 34.9 (27.5)	64, 27.7 (25.0)
12 months	35, 23.5 (23.9)	61, 22.5 (25.2)	57, 21.1 (26.3)
24 months	32, 17.1 (22.5)	62, 21.1 (28.2)	54, 14.7 (22.5)
MHI-5			
Baseline	44, 21.5 (5.5)	90, 22.7 (4.9)	80, 22.9 (4.6)
8 months	37, 24.5 (4.3)	68, 23.8 (4.8)	64, 23.8 (4.8)
12 months	35, 22.9 (4.8)	62, 23.8 (5.4)	58, 24.2 (4.6)
24 months	33, 24.1 (3.8)	62, 24.6 (4.6)	54, 25.3 (4.0)
EQ-5D			
Baseline	43, 0.448 (0.332)	89, 0.503 (0.287)	79, 0.538 (0.298)
8 months	36, 0.740 (0.143)	68, 0.691 (0.272)	67, 0.722 (0.232)
12 months	35, 0.703 (0.262)	63, 0.750 (0.257)	61, 0.778 (0.257)
24 months	34, 0.797 (0.153)	63, 0.736 (0.291)	57, 0.780 (0.304)

Outcomes in those allocated to rest then exercise but who did not complete the 10-week course before progressing to surgery

In total, 77 (36%) of the 214 participants initially randomised to rest then exercise progressed to surgery before completion of the 10-week rest-then-exercise course. Outcomes at each time point in this specific subgroup of participants are presented in *Table 24*.

TABLE 24 Health status in those who did not complete the 10-week rest-then-exercise course before progressing to surgery

Measure	Stratum A ($n = 14$), *n*, mean (SD)	Stratum B ($n = 36$), *n*, mean (SD)	Stratum C ($n = 27$), *n*, mean (SD)
OSS			
Baseline	14, 24.5 (8.8)	36, 23.3 (8.2)	27, 26.3 (8.3)
8 months	14, 39.4 (5.7)	26, 35.8 (9.7)	27, 39.4 (8.5)
12 months	13, 40.0 (8.1)	26, 39.3 (8.1)	25, 41.3 (9.3)
24 months	12, 40.7 (8.0)	25, 39.4 (10.7)	22, 42.1 (9.8)
SPADI pain			
Baseline	14, 70.0 (23.7)	35, 74.7 (19.8)	27, 72.1 (16.6)
8 months	14, 28.7 (22.1)	26, 36.0 (29.3)	27, 22.4 (23.6)
12 months	13, 20.2 (24.6)	25, 19.3 (21.4)	24, 17.2 (24.6)
24 months	11, 16.4 (23.8)	24, 25.9 (31.8)	22, 16.2 (29.4)
SPADI disability			
Baseline	14, 60.4 (27.3)	36, 65.0 (21.9)	25, 58.4 (22.9)
8 months	14, 26.4 (21.5)	25, 28.8 (27.5)	27, 20.1 (25.6)
12 months	13, 19.7 (22.7)	25, 14.7 (18.8)	25, 17.3 (26.5)
24 months	11, 16.9 (24.1)	24, 19.5 (26.8)	22, 13.6 (26.9)
SPADI			
Baseline	14, 64.1 (25.3)	36, 23.3 (8.2)	27, 26.3 (8.3)
8 months	14, 27.3 (21.2)	26, 30.9 (27.7)	27, 21.0 (24.4)
12 months	13, 19.9 (22.8)	25, 16.5 (19.5)	25, 18.3 (26.9)
24 months	11, 16.7 (23.7)	24, 22.0 (28.4)	22, 14.6 (27.6)
MHI-5			
Baseline	14, 23.3 (3.9)	36, 23.3 (4.4)	27, 23.0 (5.5)
8 months	14, 24.7 (3.3)	26, 24.1 (4.5)	26, 23.7 (5.2)
12 months	13, 23.1 (5.2)	26, 24.3 (4.1)	25, 23.6 (5.5)
24 months	11, 23.7 (4.2)	24, 24.5 (3.8)	22, 24.7 (5.2)
EQ-5D			
Baseline	14, 0.460 (0.343)	36, 0.476 (0.289)	26, 0.525 (0.306)
8 months	13, 0.817 (0.138)	26, 0.735 (0.198)	26, 0.765 (0.239)
12 months	12, 0.813 (0.138)	26, 0.754 (0.241)	25, 0.785 (0.300)
24 months	12, 0.777 (0.171)	25, 0.714 (0.311)	22, 0.812 (0.289)

Outcomes in those allocated to rest then exercise who completed the full 10-week course but still progressed to have surgery

In total, 88 (41%) of those allocated to rest then exercise completed the full 10-week course but despite this progressed to surgery. Outcomes at each time point in this specific subgroup of participants are presented in *Table 25*.

TABLE 25 Health status in those who completed the 10-week rest-then-exercise course before progressing to surgery

Measure	Stratum A ($n = 24$), *n*, mean (SD)	Stratum B ($n = 31$), *n*, mean (SD)	Stratum C ($n = 33$), *n*, mean (SD)
OSS			
Baseline	24, 21.6 (7.6)	31, 22.6 (7.0)	33, 24.8 (7.6)
8 months	20, 35.6 (8.1)	27, 34.6 (9.6)	30, 35.0 (9.5)
12 months	19, 38.3 (7.4)	24, 39.8 (8.3)	27, 39.6 (8.4)
24 months	18, 42.1 (6.8)	24, 41.8 (10.8)	25, 42.1 (7.8)
SPADI pain			
Baseline	24, 78.8 (20.2)	31, 74.6 (14.4)	33, 69.9 (18.0)
8 months	20, 39.2 (27.0)	27, 36.4 (25.5)	29, 37.1 (27.3)
12 months	18, 32.3 (30.8)	22, 22.0 (26.6)	25, 23.4 (25.0)
24 months	18, 20.4 (25.6)	24, 12.4 (25.1)	23, 15.3 (21.3)
SPADI disability			
Baseline	24, 69.2 (20.2)	31, 68.3 (18.2)	32, 59.4 (23.0)
8 months	19, 31.7 (25.9)	27, 34.5 (28.3)	29, 32.2 (24.4)
12 months	18, 25.0 (24.7)	22, 20.7 (26.2)	24, 20.8 (27.6)
24 months	18, 15.9 (23.2)	24, 13.9 (27.4)	23, 11.8 (20.0)
SPADI			
Baseline	24, 73.0 (19.1)	31, 70.8 (16.3)	33, 63.1 (20.2)
8 months	19, 34.7 (26.2)	27, 35.2 (26.8)	29, 34.0 (24.6)
12 months	18, 27.8 (26.8)	22, 21.2 (26.1)	24, 22.2 (26.2)
24 months	18, 17.6 (23.8)	24, 13.3 (26.2)	23, 13.7 (20.2)
MHI-5			
Baseline	24, 20.1 (6.4)	31, 22.6 (4.9)	33, 22.8 (4.0)
8 months	18, 24.1 (5.2)	27, 24.9 (3.8)	29, 23.5 (4.7)
12 months	18, 22.8 (4.7)	22, 24.6 (5.6)	24, 24.8 (3.5)
24 months	18, 24.8 (3.4)	24, 26.3 (3.7)	23, 25.2 (2.9)
EQ-5D			
Baseline	23, 0.386 (0.323)	30, 0.532 (0.242)	33, 0.518 (0.304)
8 months	19, 0.669 (0.116)	27, 0.726 (0.225)	29, 0.657 (0.250)
12 months	18, 0.603 (0.306)	24, 0.812 (0.165)	27, 0.780 (0.209)
24 months	18, 0.811 (0.141)	23, 0.808 (0.258)	26, 0.717 (0.354)

Outcomes in those allocated to rest then exercise who completed the full 10-week course and did not proceed to surgery

In total, 36 (17%) of those allocated to rest then exercise completed the full 10-week course and had no surgical intervention. Outcomes at each time point in this specific subgroup of participants are presented in *Table 26*. A further 14 rest-then-exercise patients withdrew from the study over the course of the study.

TABLE 26 Health status in those who completed the 10-week rest-then-exercise course and did not proceed to surgery

Measure	Stratum A ($n = 5$), *n*, mean (SD)	Stratum B ($n = 16$), *n*, mean (SD)	Stratum C ($n = 15$), *n*, mean (SD)
OSS			
Baseline	5, 32.0 (6.4)	16, 25.3 (8.4)	15, 27.7 (7.7)
8 months	5, 40.8 (3.4)	15, 35.0 (9.4)	11, 37.4 (6.5)
12 months	5, 41.2 (5.8)	14, 37.8 (9.2)	10, 38.4 (10.1)
24 months	4, 37.5 (9.6)	14, 36.5 (8.5)	9, 40.9 (5.2)
SPADI			
Baseline	5, 54.8 (19.2)	16, 69.9 (25.5)	15, 64.7 (21.5)
8 months	5, 22.4 (15.3)	14, 38.4 (30.0)	8, 30.0 (25.8)
12 months	4, 19.5 (10.0)	13, 32.5 (29.2)	9, 30.7 (27.5)
24 months	4, 20.6 (13.9)	13, 31.4 (27.5)	9, 20.0 (15.2)
SPADI disability			
Baseline	5, 42.8 (21.9)	16, 59.9 (25.2)	15, 54.3 (26.4)
8 months	5, 7.9 (5.9)	13, 35.5 (26.1)	9, 26.3 (25.7)
12 months	4, 14.1 (12.0)	12, 27.3 (24.1)	8, 26.1 (27.8)
24 months	3, 15.0 (17.4)	13, 28.1 (25.6)	9, 15.6 (16.7)
SPADI			
Baseline	5, 47.4 (18.4)	16, 63.8 (24.7)	15, 58.3 (23.4)
8 months	5, 13.5 (7.2)	13, 37.9 (26.9)	8, 27.7 (26.0)
12 months	4, 16.2 (11.1)	13, 30.9 (25.3)	8, 26.5 (27.2)
24 months	3, 15.6 (15.6)	13, 29.3 (25.9)	9, 17.3 (15.1)
MHI-5			
Baseline	5, 23.8 (3.3)	16, 22.2 (4.8)	15, 22.5 (4.4)
8 months	5, 25.8 (3.3)	14, 21.0 (6.4)	9, 25.4 (3.8)
12 months	4, 22.6 (5.1)	13, 22.0 (6.9)	9, 24.0 (4.4)
24 months	4, 22.0 (4.7)	13, 21.9 (6.2)	9, 26.8 (2.6)
EQ-5D			
Baseline	5, 0.655 (0.335)	16, 0.469 (0.345)	15, 0.603 (0.271)
8 months	4, 0.829 (0.115)	14, 0.548 (0.419)	12, 0.782 (0.116)
12 months	5, 0.800 (0.199)	12, 0.636 (0.392)	9, 0.755 (0.289)
24 months	4, 0.790 (0.187)	14, 0.674 (0.305)	9, 0.883 (0.094)

Chapter 6 Health economics

Methods: overview

The health economic analyses evaluate the total resource use and costs of rotator cuff repair and quality of life over the follow-up period of the trial. The primary economic outcome is additional cost per QALY gained of arthroscopic repair compared with open repair over a time horizon of 24 months, by ITT analysis. This outcome was assessed using patients allocated to arthroscopic and open repair in stratum A only, although cost and quality-of-life outcomes from stratum B (arthroscopic repair only) and stratum C (open repair only) are also reported. Lifetime extrapolation was not conducted for this analysis.

All analyses were conducted from the perspective of the NHS. Cost components included all initial and subsequent inpatient episodes and outpatient hospital visits, as well as GP, nurse and physiotherapist visits during follow-up.

Resource-use data collection

Resource-use for initial surgery

Individual patient data on time in theatre and number and type of bone anchors used were collected using a data collection form completed by health-care staff at the time of surgery. Additional equipment use during surgery was incorporated as a fixed cost of consumables. Further details of the assumed costs are given in *Tables 27* and *28*. The number of nights in hospital immediately following initial surgery was calculated for each patient as the difference between the date of surgery and the discharge date reported on the patient questionnaire at 2 weeks (or at 8 weeks if not reported at 2 weeks).

TABLE 27 Unit costs

Cost category	Unit cost (GB£ 2012/13)	Source and description
Rest-then-exercise programme		
Cost of rest-then-exercise programme materials	44.56	Based on actual printing costs for main trial booklets and rest-then-exercise intervention booklets, cost of envelopes for sending materials to patients, cost of a sling and set-up costs for a Freephone number
Surgery costs (all patients)[a]		
Cost per minute in theatre	16.43	Mean cost per minute in orthopaedic operating theatre. Average over 15 NHS boards in Scotland, year end March 2013. Information Services Division Scotland release 17 December 2013[75]
Cost per anchor		
Open repair	103.67/105.34	Manufacturers' list prices with a price discount applied. Costs presented are the average anchor cost for patients receiving each type of surgery (stratum A/all patients). The undiscounted list prices for the anchors ranged from £141 to £262. The illustrative average anchor cost here is based on the mean total anchor cost divided by the mean number of anchors (using imputed data)
Arthroscopic repair	107.43/107.31	
Other procedures	98.52/102.96	

continued

TABLE 27 Unit costs (*continued*)

Cost category	Unit cost (GB£ 2012/13)	Source and description
Additional fixed surgical costs		
Average cost per suture	7.14	Average of manufacturers' list prices (discounted[b]) for each suture type recorded on theatre forms
Drapes[c]	16.41	Manufacturers' list prices (discounted[b]) for shoulder arthroscopy drape and video camera drape
Fluid management system 1-day tubing[c]	20.30	Manufacturers' list prices, discounted[b]
90° suction electrode[d]	90.00	Hospital cost obtained (£90 discounted price provided by manufacturer[b])
5.5 mm full radius resector[e]	57.51	Manufacturers' list prices, discounted[b]
4.0 mm oval burr[e]	57.51	Manufacturers' list prices, discounted[b]
Monopolar diathermy ESU pencil[f]	1.93	Manufacturers' list prices, discounted[b]
Arthroscopic suture needle[g]	157.14	Cost obtained from supplier to the Nuffield Orthopaedic Centre, discounted[b]
Post-surgery and follow-up costs[a]		
Cost per inpatient bed-day	378.93	Elective inpatient excess bed-day from 2012–13 NHS reference costs ('The main schedule', 'El_XS' tab).[76] Weighted average of all shoulder and upper-arm procedures for non-trauma, 'Trauma and Orthopaedics'
Surgery during follow-up		
Repair (open)	1977.68	All calculated from the average cost for each type of procedure within the trial (cost of time in theatre, anchors and fixed equipment). The cost of nights in hospital relating to surgery during follow-up was incorporated separately
Repair (arthroscopic)	2192.80	
Repair (unknown type)	2085.24	
Reverse shoulder replacement	3722.11	Elective inpatient excess bed-day from 2012–13 NHS reference costs ('The main schedule', 'El_XS' tab).[76] Weighted average inpatient cost for major shoulder and upper-arm procedures with/without CC, non-trauma, 'Trauma and Orthopaedics'
Washout procedure	337.48	Elective inpatient excess bed-day from 2012–13 NHS reference costs ('The main schedule', 'El_XS' tab).[76] Weighted average of minor and intermediate shoulder and upper arm procedures for non-trauma, 'Trauma and Orthopaedics'
Cost per appointment with GP	37.00	Consultation lasting 11.7 minutes, including direct care staff costs, excluding qualification costs. From *Unit Costs of Health and Social Care 2013*, Table 10.8b[77]
Cost per appointment with nurse	11.34	Based on a 15.5-minute face-to-face consultation. From *Unit Costs of Health and Social Care 2013*, Table 10.6[77]
Cost per session with physiotherapist	43.69	Weighted average of NHS own costs for hospital- and community-based appointments. From 2012–13 NHS reference costs ('The main schedule', 'NCL' and 'CHSAHP' tabs)[76]
Outpatient visits (shoulder)	162.08	Weighted average outpatient cost for major, intermediate and minor outpatient procedures. From 2012–13 NHS reference costs (OPROC tab)[76]

ESU, electrosurgery unit.
a Applied to all patients according to resource use for each patient.
b An assumed price discount of 30% has been applied to the list prices to produce the cost to the hospital (as shown) for surgical items.
c All procedures.
d Mini-open repair, arthroscopic repair and all subacromial decompression, biceps tenotomy and capsular release procedures.
e Mini-open repair, arthroscopic repair and all subacromial decompression procedures.
f Open repair, mini-open repair and open partial-thickness tear procedures.
g Arthroscopic procedures only.

TABLE 28 Aggregated fixed surgical costs by procedure type (unit costs are presented in *Table 27*)

Procedure details	*n* (%)[a]	Fixed procedure costs (GB£, discounted[b])
Open repair		
Fully-open	84 (44)	39.96
Mini-open (with arthroscopic SAD)	105 (55)	244.97
Weighted average		153.98
Arthroscopic repair	190 (100)	319.64
Other procedures		
Biceps tenotomy	4 (3)	126.71
Capsular release	5 (4)	126.71
Partial-thickness tear (open)	1 (1)	38.64
SAD ± ACJ excision (arthroscopic)	112 (81)	241.72
Impossible to repair/no other procedure	6 (4)	36.71
Weighted average		222.29

ACJ, acromioclavicular joint.
a Three (1%) for open repair and 11 (8%) for other procedures were not included in the weighting because procedure details were unknown.
b An assumed price discount of 30% has been applied to the list prices to produce the cost to the hospital (as shown) for surgical items.

Resource use during follow-up

Information on health-care resource use after discharge was collected using patient questionnaires that were administered to all patients at 12 and 24 months, with responses in both questionnaires covering the 12 months prior to form completion. Data collected included the number of visits to a GP, nurse or physiotherapist/occupational therapist, the number of hospital outpatient and inpatient admissions and the number of nights in hospital; data were also collected on employment status, as reported in *Chapter 4*. Resource-use data were also available from a questionnaire administered at 8 months; however, the 12-month questionnaire also covered the 8-month follow-up period and so the 8-month responses were not used in the resource-use analysis (but they were used in the quality-of-life analysis; see later in this chapter).

Information on use of medications provided by the health-care system (mostly painkillers) was obtained from the 2-week and 8-week post-surgery questionnaires. It was assumed that the dosages reported on the questionnaires were the daily doses taken throughout the time period covered by the questionnaire responses (2 weeks for the 2-week questionnaire, 6 weeks for the 8-week questionnaire).

Data on surgical procedures during follow-up (e.g. revision repair surgery, washout for infection), along with nights spent in hospital relating to the procedures, were obtained from the 8-, 12-, and 24-month questionnaires.

Unit costs and application to resource use

Cost of initial treatment

Costs relating to surgical procedures were based on time in theatre, anchors used and nights spent in hospital after the procedure. Time in theatre was obtained from a surgery data collection form and a unit cost per minute in theatre was obtained using a national average figure for orthopaedic surgery theatres reported by the Information Services Division in Scotland.[75] List prices for the anchors used in the trial (identified by brand and product name from the surgery data collection form) were obtained from the various manufacturers and a 30% price discount was applied to these costs based on the assumption that the amount paid by the hospital would be less than the list price. The unit cost used for nights in hospital following surgery was the cost of an orthopaedic inpatient bed-day, obtained from NHS reference costs.[76]

Additional fixed equipment costs

In addition to patient-specific time in theatre and number of anchors, a fixed cost for consumables was included in the cost of initial surgery, under the assumption that the same set of single-use consumables would be used for each procedure (but varying by procedure type). This cost incorporated single-use items such as drapes, tubing and surgical devices, including bone shavers and needle passers. The surgical items used were assumed to be the same for each patient receiving a certain type of procedure (open repair, arthroscopic repair and so on). Further information on these items is given *Table 27*, with the total fixed costs given in *Table 28*. Other surgery-related resource-use items, such as theatre running costs, staffing, machinery and reusable equipment, were incorporated in the running costs per minute in theatre given in *Table 27*, which was applied using time in theatre for each patient.

Cost of revision surgery

Individual patient data on time in theatre and number of anchors were not available for revision surgery. Therefore, patients returning for a revision repair procedure were assumed to accrue a cost equal to the total procedure cost observed for the initial procedure (for the reported revision procedure type). Information on the total number of nights spent in hospital during follow-up was reported separately on the follow-up form and was assumed to include nights spent in hospital during the revision procedure.

Costs for non-repair procedures during follow-up (e.g. washout for infection, shoulder replacement) were obtained from NHS reference costs,[76] as detailed in *Table 27*.

Unit costs for other health-care resource use were obtained from national sources,[76,77] as summarised in *Table 27*.

Costs for the rest-then-exercise arm

Costs for the rest-then-exercise intervention were applied for all patients who had been allocated to the intervention (and therefore were sent the materials), regardless of their subsequent treatment.

The rest-then-exercise intervention consisted of an A4 colour booklet with information on rotator cuff tears and a management strategy of relative rest and then subsequent exercises. This was delivered by post with a sling and an accompanying CD showing moving images of the exercises. A Freephone number giving access to a shoulder physiotherapist was provided. Information on the costs of preparing, printing and distributing the booklet and CD was obtained from the trial co-ordinators in Oxford.

Application of unit costs

Unit costs were multiplied by resource use to obtain a total cost for each resource-use component and a total cost for each patient was obtained by summing all components. No further costs were accrued for patients who had died.

A discount rate of 3.5% per annum was applied to all costs accrued after 12 months, in line with standard guidelines for economic evaluations.[78] Costs are reported in UK pounds and the cost year is 2012–13.

Quality of life

Quality of life was measured at baseline and 8, 12 and 24 months using the five domains of the EQ-5D-3L questionnaire,[68,71] with patients reporting levels of mobility, self-care, usual activities, pain/discomfort and anxiety/depression using a 3-point scale. (For a summary of the proportion of responses at each level of each domain for each time point of follow-up, see *Table 38*.) The responses for the domains were converted to quality-of-life valuations using the Stata command 'eq5d' (Stata/SE version 12; StataCorp LP, College Station, TX, USA), which uses a value set based on the preferences of a large sample of the UK population to produce a EQ-5D index score for each patient at each time point. The possible range for the index scores when using the UK value set runs from –0.594 to 1, with a higher index indicating a better quality of life and an index of zero representing quality of life equivalent to death. An EQ-5D index score of zero was assumed for patients who had died.

The EQ-5D index scores were used to estimate the total QALYs for each patient between the 8-, 12- and 24-month follow-up points, as well as the total QALYs at 24 months. QALYs were calculated from the area under the curve after linear interpolation of the EQ-5D index score between time points. A discount rate was applied to QALYs after 12 months, at a rate of 3.5% per annum.[78]

Dealing with missing data

Table 29 shows the number of complete cases (individuals with complete data for all resource-use, cost and QALY outcome variables) at each follow-up point by treatment arm. Missing data were handled using multiple imputation methods. Imputation via chained equations (with the 'mi impute chained' command in Stata) was used to impute the missing values in the original data set, based on all other variables included in the imputation model, to produce a specified number of complete data sets. Three imputation models were constructed for (1) resource-use parameters (number of health-care visits and number of nights in hospital), (2) reported out-of-pocket costs (medications, transportation, private health care, lost earnings) and (3) the five EQ-5D-3L domains at each follow-up point. Thirty data sets were produced for this analysis to align with the greatest level of missingness among the imputed variables. The data sets were then combined using the 'mi estimate' command in Stata, which applies Rubin's rules when combining estimates from multiple imputed data sets to account for variation both within and between data sets. Imputation was conducted separately for initial hospitalisation, follow-up resource-use/costs and quality-of-life data. All imputation models included variables for patient characteristics (age, sex, size of tear, duration of shoulder problems at baseline) and indicators for centre and treatment allocation. For quality of life each domain of the EQ-5D-3L was imputed (rather than the index score directly) and baseline EQ-5D-3L domains were also included in the imputation model.

TABLE 29 Number (%) of complete cases by follow-up point and treatment arm in the original data

	n (%) with complete data for all outcome variables		
Follow-up point	Stratum A (*n* = 317)	Stratum B (*n* = 181)	Stratum C (*n* = 162)
At discharge[a]	199 (63)	94 (52)	92 (57)
12 months[b]	113 (36)	40 (22)	46 (28)
24 months[c]	104 (33)	36 (20)	42 (26)

a Variables included costs of theatre time, anchors, equipment and nights in hospital.
b Variables included as above plus the cost of revision surgery, out-of-pocket costs (medication, health-care visits, hospital stays) and QALYs at 12 months.
c Variables included as above plus the cost/resource-use/QALY outcome variables (as for 12 months) at 24 months.

Incremental analysis

Under conventional decision rules, specifically those used by the National Institute for Health and Care Excellence (NICE), the cost-effectiveness of a technology is assessed using the incremental cost-effectiveness ratio (ICER), which is based on the additional cost per QALY gained compared with the current best practice. The guidance for methods of economic evaluation produced by NICE[78] states that a technology with an ICER below £20,000 per QALY gained is likely to be deemed cost-effective. Technologies with ICERs above £30,000 are unlikely to be considered cost-effective unless additional justification is provided. In addition, the likelihood of a technology being accepted as cost-effective decreases as the ICER increases from £20,000 to £30,000.

Incremental cost-effectiveness ratio

The incremental analysis is presented in terms of the total additional cost per QALY gained for arthroscopic repair compared with open repair (referred to as the ICER throughout). The ICER was calculated as the difference in total costs at 24 months divided by the difference in QALYs for arthroscopic repair compared with open repair.

Analysis of uncertainty

Uncertainty around the ICER was characterised using 1000 non-parametric bootstrap replicates of the mean total cost and effect differences (adjusted for covariates for certain analyses, as detailed in the results section) between the arthroscopic repair group and the open repair group in the data. The 30 multiple imputed data sets were merged to produce one data set prior to bootstrapping.

Results

This section presents the results of the economic analysis. Resource use during initial surgery (implants, theatre time) and the follow-up period (appointments with health-care professionals, hospital visits and so on) is presented, along with the associated costs up to 24 months after surgery. Results were adjusted for covariates when specified [EQ-5D score at baseline (for QALY outcomes only), age, tear size, centre]. All results are based on imputed data unless 'original data' is specified.

Four analyses are presented for the economic outcomes:

(a) ITT, no adjustment for covariates – base case
(b) ITT, adjusting for covariates
(c) per protocol (only those patients receiving the allocated treatment), no adjustment for covariates
(d) per protocol (only those patients receiving the allocated treatment), adjusting for covariates.

Covariates for age, tear size and centre were included when calculating mean cost and effect differences for analyses (b) and (d). Effect differences for analyses (b) and (d) were also adjusted for EQ-5D index score at baseline.

Resource-use results

Resource-use results for initial surgery and during follow-up are presented in *Tables 30–32*. There were no significant differences between the arthroscopic repair group and the open repair group for any of the resource-use categories for the base-case ITT analysis, apart from outpatient visits, for which there were 0.7 (95% CI –1.5 to 0.0) fewer visits between surgery and the 12-month follow-up for the arthroscopic repair group (see *Table 31*). When adjusting for covariates this difference became non-significant.

TABLE 30 Resource-use outcomes relating to initial surgery

Resource use	Stratum A				Stratum B	Stratum C
	Arthroscopic, mean (SE)	Open, mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for age, tear size, centre)	Arthroscopic, mean (SE)	Open, mean (SE)
Results for all patients (ITT)	***(n = 136)***	***(n = 137)***			***(n = 91)***	***(n = 82)***
Time in theatre (minutes)	71.0 (4.9)	71.1 (3.6)	–0.2 (–12.1 to 11.8; 0.981)	6.8 (–1.3 to 14.9; 0.102)	75.1 (5.0)	73.9 (6.1)
Anchor quantity	1.2 (0.1)	1.4 (0.1)	–0.2 (–0.5 to 0.2; 0.352)	0.0 (–0.3 to 0.3; 0.889)	1.4 (0.2)	1.5 (0.2)
Nights in hospital	0.5 (0.1)	0.7 (0.1)	–0.1 (–0.4 to 0.2; 0.399)	–0.1 (–0.4 to 0.2; 0.578)	0.4 (0.1)	1.0 (0.1)
Results for patients treated per protocol	***(n = 63)***	***(n = 85)***			***(n = 50)***	***(n = 40)***
Time in theatre (minutes)	104.3 (4.8)	86.5 (3.4)	17.8 (6.4 to 29.2; 0.003)	14.1 (4.0 to 24.3; 0.007)	98.5 (5.0)	101.2 (8.9)
Anchor quantity	1.8 (0.1)	1.8 (0.1)	0.0 (–0.4 to –0.4; 0.954)	0.1 (–0.3 to 0.4; 0.589)	1.9 (0.2)	2.3 (0.2)
Nights in hospital	0.6 (0.1)	0.9 (0.1)	–0.2 (–0.6 to 0.1; 0.179)	–0.3 (–0.6 to 0.1; 0.176)	0.4 (0.1)	1.3 (0.2)

SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

TABLE 31 Resource-use outcomes at follow-up: ITT analysis

	Stratum A				Stratum B	Stratum C
Resource use	Arthroscopic ($n = 136$), mean (SE)	Open ($n = 137$), mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (adjusting for age, tear size, centre)	Arthroscopic ($n = 50$), mean (SE)	Open ($n = 40$), mean (SE)
Revision surgery between surgery and 12 months	0 (–)	0.0 (0.0)	–0.01 (–0.02 to 0.01; 0.320)	–0.01 (–0.02 to 0.01; 0.339)	0.01 (0.01)	0 (–)
GP visits between surgery and 12 months	1.1 (0.2)	1.2 (0.2)	–0.1 (–0.6 to 0.5; 0.831)	0.0 (–0.6 to 0.5; 0.948)	0.9 (0.2)	1.0 (0.2)
Nurse visits between surgery and 12 months	0.3 (0.1)	0.5 (0.1)	–0.2 (–0.5 to 0.1; 0.256)	–0.2 (–0.5 to 0.2; 0.354)	0.4 (0.2)	0.4 (0.1)
Physiotherapist visits between surgery and 12 months	6.1 (0.6)	6.3 (0.5)	–0.2 (–1.7 to 1.4; 0.818)	0.3 (–1.1 to 1.7; 0.685)	5.4 (0.7)	5.4 (0.8)
Inpatient visits between surgery and 12 months	0.3 (0.1)	0.4 (0.1)	–0.1 (–0.5 to 0.2; 0.418)	–0.1 (–0.5 to 0.2; 0.485)	0.3 (0.2)	0.4 (0.1)
Outpatient visits between surgery and 12 months	1.6 (0.2)	2.3 (0.3)	–0.7 (–1.5 to 0.0; 0.045)	–0.6 (–1.3 to 0.2; 0.134)	1.9 (0.4)	1.9 (0.3)
Revision surgery between 12 and 24 months	0.01 (0.01)	0.02 (0.01)	–0.01 (–0.04 to 0.02; 0.659)	0.00 (–0.04 to 0.03; 0.768)	0.01 (0.01)	0 (–)
GP visits between 12 and 24 months	0.4 (0.1)	0.4 (0.1)	0.1 (–0.2 to 0.4; 0.597)	0.1 (–0.2 to 0.4; 0.600)	0.6 (0.2)	0.5 (0.1)
Nurse visits between 12 and 24 months	0.1 (0.1)	0.1 (0.0)	0.0 (–0.1 to 0.2; 0.750)	0.0 (–0.1 to 0.1; 0.819)	0.1 (0.1)	0.1 (0.0)
Physiotherapist visits between 12 and 24 months	1.2 (0.5)	0.5 (0.2)	0.7 (–0.3 to 1.7; 0.196)	0.7 (–0.3 to 1.7; 0.160)	1.0 (0.4)	0.9 (0.3)
Inpatient visits between 12 and 24 months	0.03 (0.02)	0.00 (0.00)	0.03 (–0.02 to 0.08)	0.03 (–0.02 to 0.08)	0.01 (0.01)	0.00 (0.00)
Outpatient visits between 12 and 24 months	0.4 (0.1)	0.2 (0.1)	0.2 (–0.1 to 0.5; 0.282)	0.2 (–0.1 to 0.5; 0.212)	0.3 (0.1)	0.3 (0.1)

SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

TABLE 32 Resource-use outcomes at follow-up: per-protocol analysis

Resource use	Stratum A				Stratum B	Stratum C
	Arthroscopic ($n = 63$), mean (SE)	Open ($n = 85$), mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for age, tear size, centre)	Arthroscopic ($n = 50$), mean (SE)	Open ($n = 40$), mean (SE)
Revision surgery between surgery and 12 months	0 (–)	0.01 (0.01)	–0.01 (–0.04 to 0.02; 0.391)	–0.01 (–0.04 to 0.01; 0.327)	0.02 (0.02)	0 (–)
GP visits between surgery and 12 months	1.0 (0.2)	1.4 (0.2)	–0.3 (–1.0 to 0.4; 0.356)	–0.2 (–0.9 to 0.5; 0.567)	0.8 (0.3)	1.1 (0.4)
Nurse visits between surgery and 12 months	0.5 (0.2)	0.8 (0.2)	–0.3 (–0.9 to 0.3; 0.308)	–0.4 (–1.0 to 0.3; 0.251)	0.5 (0.2)	0.4 (0.2)
Physiotherapist visits between surgery and 12 months	7.7 (0.8)	8.0 (0.7)	–0.3 (–2.2 to 1.8; 0.800)	0.4 (–1.7 to 2.4; 0.728)	6.3 (0.9)	6.8 (1.1)
Inpatient visits between surgery and 12 months	0.5 (0.2)	0.6 (0.2)	–0.2 (–0.7 to 0.4; 0.596)	–0.3 (–0.9 to 0.3; 0.373)	0.2 (0.2)	0.4 (0.1)
Outpatient visits between surgery and 12 months	1.9 (0.3)	2.9 (0.5)	–1.0 (–2.2 to 0.2; 0.111)	–0.7 (–1.9 to 0.6; 0.283)	1.6 (0.4)	2.2 (0.5)
Revision surgery between 12 and 24 months	0.03 (0.02)	0.04 (0.02)	0.00 (–0.06 to 0.06; 0.907)	–0.01 (–0.08 to 0.06; 0.777)	0.02 (0.02)	0 (–)
GP visits between 12 and 24 months	0.4 (0.2)	0.4 (0.2)	0.0 (–0.5 to 0.4; 0.936)	0.1 (–0.5 to 0.5; 0.981)	0.5 (0.3)	0.6 (0.2)
Nurse visits between 12 and 24 months	0.0 (0.0)	0.1 (0.1)	–0.1 (–0.2 to 0.1; 0.369)	–0.1 (–0.2 to 0.1; 0.388)	0.1 (0.1)	0.1 (0.1)
Physiotherapist visits between 12 and 24 months	1.9 (1.0)	0.7 (0.3)	1.3 (–0.5 to 3.0; 0.165)	1.4 (–0.4 to 3.2; 0.116)	1.0 (0.5)	0.9 (0.4)
Inpatient visits between 12 and 24 months	0 (–)	0 (–)	NA	NA	0.02 (0.02)	0.00 (0.00)
Outpatient visits between 12 and 24 months	0.5 (0.3)	0.3 (0.1)	0.2 (–0.3 to 0.7; 0.488)	0.2 (–0.2 to 0.7; 0.334)	0.3 (0.2)	0.4 (0.2)

NA, not applicable; SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

For the per-protocol analysis there was a significant difference in theatre time between patients receiving an arthroscopic repair and patients receiving an open repair, at a mean of 17.8 (95% CI 6.4 to 29.2) minutes longer for arthroscopic repair when not adjusting for covariates and 14.1 (95% CI 4.0 to 24.3) minutes longer for arthroscopic repair when adjusting for covariates (see *Table 30*). However, none of the other resource-use categories for either initial surgery or follow-up were significantly different between the two treatment groups (see *Tables 30* and *32*).

Cost results

Intention-to-treat analysis

Cost outcomes for initial surgery for the base-case ITT analysis are presented in *Table 33*. For the ITT analysis the difference in total initial procedure-related costs between treatment groups was not significant at the $p = 0.05$ level, whether adjusting for covariates or not.

The difference in total cost of surgery alone (excluding the cost of nights in hospital after the procedure) was non-significant without covariate adjustment in the base case but significant when adjusted for covariates, at a mean of £187 (95% CI £35 to £339) more costly for the arthroscopic repair group than the open repair group. Additional equipment costs were significantly more costly for arthroscopic repair, being £58 (95% CI £31 to £84) more costly for arthroscopic repair without covariate adjustment and £77 (95% CI £56 to £97) more costly for arthroscopic repair with covariate adjustment.

Follow-up costs to 24 months for the base-case ITT analysis are presented in *Table 34*. The only resource-use category that had a significance cost difference between groups was outpatient visits, which were £121 (95% CI £2 to £240) less costly between surgery and 12 months' follow-up for the arthroscopic group than for the open repair group (without adjustment for covariates). When adjusting for covariates this difference became non-significant. There were no significant differences in mean cost between the arthroscopic repair group and the open repair group for any other component resource-use category, nor were there any significant differences in total follow-up costs at 12 months or 24 months. The total time-discounted mean cost difference between arthroscopic repair and open repair at 24 months for the unadjusted base-case ITT analysis was negative at –£132 (95% CI –£589 to £324), suggesting that arthroscopic repair is less costly overall. The difference was positive after adjusting for covariates (£105, 95% CI –£255 to £466), suggesting that arthroscopic repair is more costly overall, although both results were non-significant.

Per-protocol analysis

For the per-protocol analysis there was a significant difference in the total initial procedure-related cost between the arthroscopic repair group and the open repair group, at £371 (95% CI £135 to £607) more costly for arthroscopic repair with no covariate adjustment and £315 (95% CI £93 to £536) more costly for arthroscopic repair with covariate adjustment (see *Table 33*).

The total cost of surgery alone (excluding nights in hospital) was also significantly different between the two groups, at £463 (95% CI £260 to £666) more costly for arthroscopic repair without covariate adjustment and £410 (95% CI £232 to £589) more costly for arthroscopic repair with covariate adjustment. This difference was largely driven by the longer theatre time for the arthroscopic repair group. The cost of theatre time was significantly different between the two treatment groups, in line with the resource-use outcomes for time in theatre. Theatre time was £292 (95% CI £105 to £479) more costly for arthroscopic repair without covariate adjustment and £232 (95% CI £66 to £399) more costly for arthroscopic repair with covariate adjustment.

Follow-up costs to 24 months for the per-protocol analysis are presented in *Table 35*. There were no significant differences between the two treatment groups for any of the cost components. The mean total cost at 24 months was greater for arthroscopic repair by £222 (95% CI –£328 to £773) without covariate adjustment and by £207 (95% CI –£341 to £754) with covariate adjustment, suggesting that arthroscopic repair is more costly over the follow-up period, although again neither outcome was significant.

TABLE 33 Cost outcomes relating to initial surgery

Cost item	Stratum A (£)				Stratum B (£)	Stratum C (£)
	Arthroscopic, mean (SE)	Open, mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for age, tear size, centre)	Arthroscopic, mean (SE)	Open, mean (SE)
Results for all patients (ITT analysis)	***(n = 136)***	***(n = 137)***			***(n = 91)***	***(n = 82)***
Theatre time	1166 (80)	1169 (60)	–2 (–199 to 194; 0.981)	111 (–22 to 244; 0.102)	1233 (83)	1214 (100)
Anchor costs	127 (14)	147 (14)	–20 (–56 to 17; 0.288)	–1 (–29 to 28; 0.959)	145 (18)	158 (22)
Equipment costs	202 (12)	145 (7)	58 (31 to 84; 0.000)	77 (56 to 97; 0.000)	237 (13)	164 (9)
Total cost of surgery	1497 (96)	1460 (71)	36 (–200 to 271; 0.766)	187 (35 to 339; 0.016)	1615 (102)	1536 (115)
Nights in hospital	206 (46)	255 (36)	–49 (–165 to 66; 0.399)	–32 (–147 to 82; 0.578)	144 (38)	365 (54)
Total procedure-related costs	1701 (115)	1715 (86)	–14 (–297 to 270; 0.924)	155 (–45 to 354; 0.129)	1760 (113)	1900 (142)
Results for patients treated per protocol	***(n = 63)***	***(n = 85)***			***(n = 50)***	***(n = 40)***
Theatre time	1714 (78)	1422 (56)	292 (105 to 479; 0.003)	232 (66 to 399; 0.007)	1619 (82)	1663 (146)
Anchor costs	198 (14)	193 (15)	5 (–36 to 47; 0.799)	12 (–24 to 49; 0.507)	201 (17)	245 (22)
Equipment costs	320 (–)	154 (–)	166 (–)	166 (–)	320 (–)	154 (–)
Total cost of surgery	2231 (83)	1768 (63)	463 (260 to 666; 0.000)	410 (232 to 589; 0.000)	2139 (89)	2062 (152)
Nights in hospital	231 (48)	323 (46)	–92 (–227 to 43; 0.179)	–96 (–235 to 44; 0.176)	166 (51)	477 (77)
Total procedure-related costs	2462 (90)	2091 (75)	371 (135 to 607; 0.002)	315 (93 to 536; 0.006)	2306 (102)	2539 (180)

SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

TABLE 34 Cost outcomes for follow-up: ITT analysis

Cost item	Stratum A (£)				Stratum B (£)	Stratum C (£)
	Arthroscopic ($n = 136$), mean (SE)	Open ($n = 137$), mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (adjusting for age, tear size, centre)	Arthroscopic ($n = 91$), mean (SE)	Open ($n = 82$), mean (SE)
Revision surgery between surgery and 12 months	0 (–)	2 (2)	–2 (–7 to 2; 0.320)	–2 (–7 to 3; 0.339)	41 (41)	0 (–)
GP visits between surgery and 12 months	40 (7)	43 (6)	–2 (–22 to 18; 0.831)	–1 (–21 to 19; 0.948)	34 (8)	38 (9)
Nurse visits between surgery and 12 months	4 (1)	6 (2)	–2 (–6 to 2; 0.256)	–2 (–6 to 2; 0.354)	5 (2)	5 (1)
Physiotherapist visits between surgery and 12 months	267 (24)	275 (24)	–8 (–75 to 59; 0.818)	13 (–49 to 74; 0.685)	234 (31)	235 (33)
Inpatient visits between surgery and 12 months	119 (37)	170 (51)	–52 (–178 to 74; 0.418)	–45 (–173 to 83; 0.485)	113 (64)	169 (46)
Outpatient visits between surgery and 12 months	259 (31)	380 (52)	–121 (–240 to -2; 0.045)	–92 (–213 to 29; 0.134)	312 (64)	306 (49)
Medication costs between surgery and 12 months	6 (1)	4 (1)	1 (–2 to 5; 0.386)	2 (–2 to 5; 0.336)	7 (2)	6 (3)
Cost after surgery to 12-month follow-up	694 (66)	881 (93)	–187 (–413 to 40; 0.106)	–128 (–350 to 94; 0.256)	745 (138)	758 (93)
Total cost up to 12 months	2395 (149)	2596 (142)	–200 (–607 to 207; 0.333)	26 (–283 to 337; 0.867)	2055 (182)	2659 (194)
Revision surgery between 12 and 24 months	30 (21)	31 (22)	–1 (–60 to 59; 0.986)	4 (–58 to 66; 0.899)	0 (–)	0 (–)
GP visits between 12 and 24 months	17 (5)	13 (4)	3 (–9 to 15; 0.597)	3 (–9 to 16; 0.600)	23 (7)	19 (5)
Nurse visits between 12 and 24 months	1 (1)	1 (0)	0 (–1 to 2; 0.750)	0 (–1 to 2; 0.819)	1 (1)	1 (0)
Physiotherapist visits between 12 and 24 months	51 (21)	23 (8)	29 (–15 to 72; 0.196)	31 (–12 to 75; 0.160)	44 (17)	38 (12)
Inpatient visits between 12 and 24 months	12 (9)	0 (–)	11 (–6 to 29; 0.209)	12 (–6 to 30; 0.198)	4 (4)	1 (10)
Outpatient visits between 12 and 24 months	67 (23)	39 (12)	27 (–23 to 77; 0.282)	31 (–18 to 80; 0.212)	54 (24)	44 (18)
Total cost from 12 to 24 months	177 (59)	107 (30)	70 (–59 to 200; 0.268)	82 (–49 to 212; 0.219)	127 (40)	103 (28)
Total cost over 24 months	2573 (177)	2703 (150)	–130 (–589 to 329; 0.578)	108 (–255 to 471; 0.558)	2632 (195)	2762 (201)
Total cost over 24 months (discounted)	2567 (176)	2699 (149)	–132 (–589 to 324; 0.569)	105 (–255 to 466; 0.565)	2628 (194)	2758 (201)

SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

TABLE 35 Cost outcomes for follow-up: per-protocol analysis

Cost item	Stratum A (£)				Stratum B (£)	Stratum C (£)
	Arthroscopic ($n = 63$), mean (SE)	Open ($n = 85$), mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] p-value) (adjusting for age, tear size, centre)	Arthroscopic ($n = 50$), mean (SE)	Open ($n = 40$), mean (SE)
Revision surgery between surgery and 12 months	0 (–)	4 (4)	–4 (–13 to 5; 0.391)	–5 (–15 to 5; 0.327)	74 (74)	0 (–)
GP visits between surgery and 12 months	38 (9)	50 (9)	–12 (–37 to 13; 0.356)	–8 (–35 to 19; 0.567)	30 (10)	39 (14)
Nurse visits between surgery and 12 months	5 (2)	9 (2)	–3 (–10 to 3; 0.308)	–4 (–11 to 3; 0.245)	6 (3)	4 (2)
Physiotherapist visits between surgery and 12 months	337 (33)	348 (29)	–11 (–99 to 76; 0.800)	16 (–73 to 105; 0.728)	273 (40)	296 (48)
Inpatient visits between surgery and 12 months	181 (74)	240 (78)	–59 (–278 to 160; 0.596)	–103 (–333 to 126; 0.373)	84 (62)	164 (57)
Outpatient visits between surgery and 12 months	313 (54)	469 (74)	–157 (–350 to 37; 0.111)	–111 (–315 to 93; 0.283)	263 (64)	358 (77)
Medication costs between surgery and 12 months	7 (2)	5 (1)	1 (–3 to 6; 0.529)	1 (–3 to 5; 0.662)	6 (2)	8 (4)
Cost after surgery to 12 month follow-up	881 (109)	1126 (131)	–245 (–599 to 109; 0.174)	–215 (–583 to 154; 0.251)	736 (164)	869 (135)
Total cost over 12 months	3343 (141)	3217 (159)	126 (–316 to 569; 0.573)	100 (–340 to 540; 0.653)	3042 (208)	3408 (258)
Revision surgery between 12 and 24 months	65 (46)	50 (35)	16 (–96 to 127; 0.782)	9 (–114 to 132; 0.882)	0 (–)	0 (–)
GP visits between 12 and 24 months	15 (6)	15 (6)	–1 (–17 to 16; 0.936)	0 (–18 to 18; 0.981)	19 (10)	23 (8)
Nurse visits between 12 and 24 months	0 (–)	1 (1)	–1 (–2 to 1; 0.369)	–1 (–2 to 1; 0.388)	1 (1)	1 (1)
Physiotherapist visits between 12 and 24 months	84 (43)	29 (12)	55 (–23 to 132; 0.165)	63 (–16 to 142; 0.116)	44 (22)	39 (16)
Inpatient visits between 12 and 24 months	0 (–)	0 (–)	NA	NA	8 (8)	1 (2)
Outpatient visits between 12 and 24 months	82 (44)	53 (17)	30 (–55 to 115; 0.488)	39 (–40 to 118; 0.334)	54 (29)	63 (33)
Total cost from 12 to 24 months	247 (119)	148 (46)	99 (–128 to 327; 0.391)	110 (–126 to 347; 0.357)	126 (50)	127 (48)
Total cost over 24 months	3590 (226)	3365 (171)	226 (–330 to 781; 0.423)	210 (–342 to 763; 0.452)	3168 (229)	3534 (269)
Total cost over 24 months (discounted)	3582 (223)	3360 (171)	222 (–328 to 773; 0.426)	207 (–341 to 754; 0.456)	3164 (228)	3530 (268)

NA, not applicable; SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

Quality-of-life results

Table 36 presents a summary of the mean EQ-5D index score at each follow-up point (8, 12 and 24 months). The proportions of responses at each level of the five domains at each time point are presented in *Tables 37–40* for the non-imputed data and in *Tables 41–44* for the imputed data. QALYs from baseline to 24 months' follow-up are presented in *Table 45*.

Intention-to-treat analysis

For the base-case ITT analysis, there were no significant differences in total QALYs between the arthroscopic repair group and the open repair group at 8, 12 or 24 months. The mean difference in total QALYs between the groups at 24 months with time discounting was negative, both without (0.00, 95% CI –0.11 to 0.10) and with (–0.04, 95% CI –0.12 to 0.05) adjustment for covariates, suggesting worse outcomes for the arthroscopic repair group, although both values were non-significant.

Per-protocol analysis

There were no significant differences between the two groups in the per-protocol analysis for any of the quality-of-life outcomes. Again, the mean difference in total QALYs between the groups was negative for both the unadjusted analysis (–0.03, 95% CI –0.17 to 0.12) and the adjusted analysis (–0.06, 95% CI –0.17 to 0.06), suggesting that arthroscopic repair may be less effective, although again both results were non-significant.

TABLE 36 European Quality of Life-5 Dimensions index scores

	Stratum A					Stratum B	Stratum C
Time point	Arthroscopic, mean (SE)	Open, mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for baseline EQ-5D index)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for baseline EQ-5D index, age, tear size, centre)	Arthroscopic, mean (SE)	Open, mean (SE)
Results for all patients (ITT)	***(n = 136)***	***(n = 137)***				***(n = 91)***	***(n = 82)***
Baseline	0.55 (0.03)	0.52 (0.02)	0.03 (–0.04 to 0.10; 0.352)	NA	0.03 (–0.04 to 0.11; 0.336)[b]	0.51 (0.03)	0.54 (0.03)
8 months	0.68 (0.03)	0.69 (0.02)	–0.01 (–0.08 to 0.05; 0.691)	–0.03 (–0.09 to 0.04; 0.391)	–0.03 (–0.09 to 0.04; 0.392)	0.69 (0.03)	0.70 (0.02)
12 months	0.72 (0.02)	0.71 (0.03)	0.01 (–0.06 to 0.08; 0.852)	–0.01 (–0.07 to 0.06; 0.878)	–0.01 (–0.08 to 0.06; 0.788)	0.70 (0.03)	0.73 (0.03)
24 months	0.74 (0.02)	0.76 (0.02)	–0.03 (–0.09 to 0.03; 0.389)	–0.04 (–0.09 to 0.02; 0.218)	–0.04 (–0.10 to 0.02; 0. 232)	0.72 (0.03)	0.74 (0.03)
Results for patients (per protocol)	***(n = 63)***	***(n = 85)***				***(n = 50)***	***(n = 40)***
Baseline	0.53 (0.04)	0.50 (0.03)	0.03 (–0.07 to 0.13; 0.579)	NA	0.02 (–0.08 to 0.12; 0.663)[b]	0.51 (0.05)	0.47 (0.05)
8 months	0.67 (0.04)	0.70 (0.03)	–0.03 (–0.13 to 0.06; 0.519)	–0.04 (–0.13 to 0.04; 0.326)	–0.03 (–0.12 to 0.06; 0.494)	0.72 (0.03)	0.65 (0.04)
12 months	0.71 (0.04)	0.72 (0.03)	–0.00 (–0.10 to 0.09; 0.952)	–0.01 (–0.10 to 0.08; 0.786)	–0.03 (–0.11 to 0.06; 0.569)	0.76 (0.03)	0.71 (0.04)
24 months	0.74 (0.03)	0.78 (0.02)	–0.04 (–0.12 to 0.04; 0.353)	–0.05 (–0.12 to 0.03; 0.256)	–0.05 (–0.13 to 0.03; 0.188)	0.74 (0.04)	0.75 (0.04)

NA, not applicable; SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.
b Not adjusted for baseline EQ-5D score (EQ-5D_index_BL), only for age, tear size and centre.

TABLE 37 Number (%) of responses for each level in each domain of the EQ-5D questionnaire: original data, all strata

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	505 (77)	358 (54)	90 (14)	16 (2)	427 (65)
2	152 (23)	299 (45)	519 (79)	474 (72)	207 (31)
3	–	2 (0)	51 (8)	169 (26)	25 (4)
Missing	3 (0)	1 (0)	–	1 (0)	1 (0)
8 months					
1	437 (66)	413 (63)	241 (37)	142 (22)	412 (63)
2	141 (21)	158 (24)	309 (47)	399 (61)	151 (23)
3	–	5 (1)	27 (4)	35 (5)	12 (2)
Missing	80 (12)	82 (12)	81 (12)	82 (12)	83 (13)
12 months					
1	414 (63)	443 (67)	290 (44)	194 (29)	408 (62)
2	145 (22)	112 (17)	247 (38)	323 (49)	137 (21)
3	1 (0)	3 (0)	24 (4)	42 (6)	12 (2)
Missing	98 (15)	100 (15)	97 (15)	99 (15)	101 (15)
24 months					
1	387 (59)	449 (69)	308 (47)	232 (36)	414 (63)
2	155 (24)	90 (14)	219 (34)	283 (43)	119 (18)
3	–	4 (1)	16 (2)	28 (4)	9 (1)
Missing	111 (17)	110 (17)	110 (17)	110 (17)	111 (17)

TABLE 38 Number (%) of responses for each level in each domain of the EQ-5D questionnaire: original data, stratum A

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	244 (77)	176 (56)	45 (14)	9 (3)	209 (66)
2	72 (23)	139 (44)	252 (80)	223 (70)	95 (30)
3	–	2 (1)	20 (6)	84 (27)	12 (4)
Missing	1 (0)	–	–	1 (0)	1 (0)
8 months					
1	216 (68)	210 (66)	115 (36)	72 (23)	194 (61)
2	68 (22)	67 (21)	155 (49)	193 (61)	81 (26)
3	–	5 (2)	15 (5)	19 (6)	8 (3)
Missing	32 (10)	34 (11)	31 (10)	32 (10)	33 (10)
12 months					
1	202 (64)	220 (70)	137 (43)	95 (30)	202 (64)
2	75 (24)	55 (17)	129 (41)	161 (51)	70 (22)
3	1 (0)	3 (1)	14 (4)	24 (8)	6 (2)
Missing	38 (12)	38 (12)	36 (11)	36 (11)	38 (12)
24 months					
1	191 (61)	224 (71)	151 (48)	107 (34)	203 (65)
2	77 (25)	42 (13)	112 (36)	153 (49)	61 (19)
3	–	2 (1)	5 (2)	8 (3)	4 (1)
Missing	46 (15)	46 (15)	46 (15)	46 (15)	46 (15)

TABLE 39 Number (%) of responses for each level in each domain of the EQ-5D questionnaire: original data, stratum B

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	132 (73)	91 (50)	25 (14)	5 (3)	110 (61)
2	48 (27)	90 (50)	141 (78)	127 (70)	65 (36)
3	–	–	15 (8)	49 (27)	6 (3)
Missing	1 (1)	–	–	–	–
8 months					
1	111 (61)	101 (56)	73 (40)	36 (20)	110 (61)
2	39 (22)	49 (27)	71 (39)	101 (56)	37 (20)
3	–	–	4 (2)	12 (7)	3 (2)
Missing	31 (17)	31 (17)	33 (18)	32 (18)	31 (17)
12 months					
1	105 (58)	112 (62)	70 (39)	49 (27)	103 (57)
2	42 (23)	34 (19)	73 (40)	83 (46)	38 (21)
3	–	–	4 (2)	13 (7)	4 (2)
Missing	34 (19)	35 (19)	34 (19)	36 (20)	36 (20)
24 months					
1	100 (56)	116 (65)	80 (45)	62 (35)	108 (61)
2	42 (24)	26 (15)	56 (31)	71 (40)	33 (19)
3	–	1 (1)	7 (4)	10 (6)	2 (1)
Missing	36 (20)	35 (20)	35 (20)	35 (20)	35 (20)

TABLE 40 Number (%) of responses for each level in each domain of the EQ-5D questionnaire: original data, stratum C

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	129 (80)	91 (56)	20 (12)	2 (1)	108 (67)
2	32 (20)	70 (43)	126 (78)	124 (77)	47 (29)
3	–	–	16 (10)	36 (22)	7 (4)
Missing	1 (1)	1 (1)	–	–	–
8 months					
1	110 (68)	102 (63)	53 (33)	34 (21)	108 (67)
2	34 (21)	42 (26)	83 (52)	105 (65)	33 (21)
3	–	–	8 (5)	4 (2)	1 (1)
Missing	17 (11)	17 (11)	17 (11)	18 (11)	19 (12)
12 months					
1	107 (66)	111 (69)	83 (52)	50 (31)	103 (64)
2	28 (17)	23 (14)	45 (28)	79 (49)	29 (18)
3	–	–	6 (4)	5 (3)	2 (1)
Missing	26 (16)	27 (17)	27 (17)	27 (17)	27 (17)
24 months					
1	96 (60)	109 (68)	77 (48)	63 (39)	103 (64)
2	36 (22)	22 (14)	51 (32)	59 (37)	25 (16)
3	–	1 (1)	4 (2)	10 (6)	3 (2)
Missing	29 (18)	29 (18)	29 (18)	29 (18)	30 (19)

TABLE 41 Percentage (SE) of responses for each level in each domain of the EQ-5D questionnaire: imputed data, all strata

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	76.9 (1.6)	54.3 (1.9)	13.6 (1.3)	2.4 (0.6)	64.8 (1.9)
2	23.1 (1.6)	45.4 (1.9)	78.6 (1.6)	71.9 (1.8)	31.4 (1.8)
3					
Missing	–	0.3 (0.2)	7.7 (1.0)	25.6 (1.7)	3.8 (0.7)
8 months					
1	75.3 (1.8)	71.2 (1.9)	41.4 (2.0)	24.4 (1.8)	71.2 (1.9)
2	24.7 (1.8)	27.9 (1.9)	53.8 (2.1)	69.4 (1.9)	26.6 (1.8)
3					
Missing	–	1.0 (0.4)	4.9 (0.9)	6.2 (1.0)	2.2 (0.6)
12 months					
1	73.5 (1.8)	78.7 (1.7)	51.2 (2.1)	34.3 (2.0)	73.1 (1.8)
2	26.2 (1.9)	20.7 (1.7)	44.3 (2.1)	57.7 (2.1)	24.6 (1.8)
3	0.3 (0.3)	0.6 (0.4)	4.5 (0.9)	8.0 (1.1)	2.3 (0.6)
Missing	73.5 (1.8)	78.7 (1.7)	51.2 (2.1)	34.3 (2.0)	73.1 (1.8)
24 months					
1	69.9 (1.9)	81.7 (1.7)	55.8 (2.0)	42.6 (2.1)	75.5 (1.8)
2	30.1 (1.9)	17.5 (1.6)	41.0 (2.0)	51.9 (2.2)	22.6 (1.8)
3	–	0.8 (0.4)	3.2 (0.8)	5.5 (1.0)	1.9 (0.6)
Missing	69.9 (1.9)	81.7 (1.7)	55.8 (2.0)	42.6 (2.1)	75.5 (1.8)

TABLE 42 Percentage (SE) of responses for each level in each domain of the EQ-5D questionnaire: imputed data, stratum A

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	77.2 (2.4)	55.5 (28.0)	14.2 (2.0)	2.8 (0.9)	66.2 (2.7)
2	22.8 (2.4)	43.8 (2.8)	79.5 (2.3)	70.6 (2.6)	30.0 (2.6)
3	–	0.6 (0.4)	6.3 (1.4)	26.6 (2.5)	3.8 (1.1)
8 months					
1	75.8 (2.5)	73.9 (2.6)	40.2 (2.9)	25.1 (2.6)	68.6 (2.7)
2	24.2 (2.5)	24.4 (2.6)	54.5 (3.0)	68.3 (2.7)	28.6 (2.7)
3	–	1.6 (0.7)	5.3 (1.3)	6.6 (1.5)	2.8 (0.9)
12 months					
1	72.3 (2.7)	78.5 (2.5)	48.9 (2.9)	33.8 (2.8)	72.6 (2.6)
2	27.2 (2.7)	20.5 (2.4)	45.9 (2.9)	57.3 (2.9)	25.1 (25.7)
3	0.5 (0.4)	1.1 (0.6)	5.2 (1.3)	8.9 (1.7)	2.3 (0.9)
24 months					
1	69.6 (2.8)	82.0 (2.3)	55.5 (3.0)	39.7 (2.9)	74.7 (2.6)
2	30 4 (2.8)	17.1 (2.3)	42.2 (3.0)	56.4 (3.0)	23.5 (2.5)
3	–	1.0 (0.6)	2.3 (0.9)	3.9 (1.2)	1.7 (0.8)

TABLE 43 Percentage (SE) of responses for each level in each domain of the EQ-5D questionnaire: imputed data, stratum B

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	73.4 (3.3)	50.3 (3.7)	13.8 (2.6)	2.8 (1.2)	60.8 (3.6)
2	26.6 (3.3)	49.7 (3.7)	77.9 (3.1)	70.2 (3.4)	35.9 (3.6)
3	–	–	8.3 (2.1)	27.1 (3.3)	3.3 (1.3)
8 months					
1	73.7 (3.5)	67.2 (2.2)	47.6 (3.9)	23.7 (3.3)	72.1 (3.5)
2	26.3 (3.5)	32.3 (2.4)	49.0 (4.0)	68.1 (3.8)	25.7 (3.4)
3	–	0.5 (0.7)	3.4 (1.6)	8.2 (2.3)	2.2 (1.2)
12 months					
1	71.7 (2.5)	76.9 (1.9)	47.7 (4.2)	33.2 (3.8)	71.2 (3.6)
2	28.1 (2.6)	23.0 (2.0)	49.1 (4.2)	57.6 (4.0)	26.1 (3.4)
3	0.1 (0.5)	0.1 (0.4)	3.2 (1.5)	9.2 (2.3)	2.8 (1.3)
24 months					
1	68.5 (3.8)	80.9 (3.2)	55.1 (4.1)	43.4 (4.1)	74.7 (3.5)
2	31.5 (2.8)	18.4 (3.1)	40.2 (4.2)	49.8 (4.2)	23.5 (3.4)
3	–	0.7 (0.7)	4.7 (1.7)	6.7 (2.0)	1.8 (1.2)

TABLE 44 Percentage (SE) of responses for each level in each domain of the EQ-5D questionnaire: imputed data, stratum C

Level	Mobility	Self-care	Activity	Pain	Anxiety
Baseline					
1	80.1 (3.2)	56.5 (3.9)	12.3 (2.6)	1.2 (0.9)	66.7 (3.7)
2	19.9 (3.2)	43.5 (3.9)	77.8 (3.3)	76.5 (3.3)	29.0 (3.6)
3	–	–	9.9 (2.4)	22.2 (3.3)	4.3 (1.6)
8 months					
1	76.0 (3.6)	70.2 (2.1)	36.6 (4.0)	23.6 (3.6)	75.3 (3.6)
2	24.0 (3.6)	29.7 (2.0)	57.8 (4.0)	73.1 (3.8)	23.8 (3.5)
3	–	0.1 (0.5)	5.5 (1.9)	3.3 (1.6)	0.9 (0.8)
12 months					
1	78.0 (2.1)	81.1 (1.7)	59.6 (4.1)	36.5 (4.1)	76.2 (3.6)
2	21.9 (2.1)	18.8 (1.6)	35.7 (4.1)	58.6 (4.2)	22.1 (3.5)
3	0.0 (0.3)	0.2 (0.7)	4.6 (1.8)	4.9 (1.9)	1.7 (1.2)
24 months					
1	72.0 (3.7)	81.9 (3.4)	57.3 (4.1)	47.4 (4.2)	78.0 (3.5)
2	28.0 (3.7)	17.3 (3.3)	39.5 (4.1)	45.5 (4.2)	19.9 (3.4)
3	–	0.8 (0.8)	3.1 (1.5)	7.1 (2.1)	2.2 (1.3)

TABLE 45 Quality-of-life outcomes: QALYs

	Stratum A					Stratum B	Stratum C
Time point	Arthroscopic, mean (SE)	Open, mean (SE)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (base case, no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for baseline EQ-5D index)	Arthroscopic vs. open mean difference (95% CI;[a] *p*-value) (adjusting for baseline EQ-5D index, age, tear size, centre)	Arthroscopic, mean (SE)	Open, mean (SE)
Results for all patients (ITT)	***(n = 136)***	***(n = 137)***				***(n = 91)***	***(n = 82)***
QALYs from baseline to 8 months	0.41 (0.01)	0.40 (0.01)	0.01 (–0.03 to 0.05; 0.740)	–0.01 (–0.03 to 0.01; 0.391)	–0.01 (–0.03 to 0.01; 0.392)	0.40 (0.02)	0.41 (0.02)
QALYs from 8 months to 12 months	0.23 (0.01)	0.23 (0.01)	–0.00 (–0.02 to 0.02; 0.911)	–0.01 (–0.02 to 0.13; 0.575)	–0.01 (–0.03 to 0.01; 0.529)	0.23 (0.01)	0.24 (0.01)
QALYs from 12 months to 24 months	0.73 (0.02)	0.74 (0.02)	–0.01 (–0.07 to 0.05; 0.734)	–0.02 (–0.07 to 0.03; 0.449)	–0.02 (–0.08 to 0.03; 0.414)	0.71 (0.03)	0.74 (0.03)
Total QALYs over 24 months	1.37 (0.04)	1.37 (0.04)	0.00 (–0.11 to 0.10; 0.931)	–0.04 (–0.12 to 0.05; 0.423)	–0.04 (–0.12 to 0.05; 0.392)	1.34 (0.05)	1.39 (0.04)
Total QALYs over 24 months (time discounted)	1.34 (0.04)	1.35 (0.04)	0.00 (–0.11 to 0.10; 0.935)	–0.03 (–0.12 to 0.05; 0.423)	–0.04 (–0.12 to 0.05; 0.392)	1.32 (0.05)	1.36 (0.04)
Results for patients (per protocol)	***(n = 63)***	***(n = 85)***				***(n = 50)***	***(n = 40)***
QALYs from baseline to 8 months	0.40 (0.02)	0.40 (0.02)	0.00 (–0.06 to 0.05; 0.964)	–0.01 (–0.04 to 0.01; 0.326)	–0.01 (–0.04 to 0.02; 0.494)	0.41 (0.02)	0.38 (0.02)
QALYs from 8 months to 12 months	0.23 (0.01)	0.24 (0.01)	–0.01 (–0.03 to 0.02; 0.697)	–0.01 (–0.04 to 0.02; 0.484)	–0.01 (–0.03 to 0.02; 0.473)	0.25 (0.01)	0.23 (0.01)
QALYs from 12 months to 24 months	0.73 (0.03)	0.75 (0.03)	–0.02 (–0.10 to 0.06; 0.612)	–0.03 (–0.10 to 0.05; 0.449)	–0.04 (–0.11 to 0.03; 0.291)	0.75 (0.03)	0.73 (0.04)
Total QALYs over 24 months	1.36 (0.06)	1.39 (0.04)	–0.03 (–0.18 to 0.12; 0.713)	–0.05 (–0.17 to 0.07; 0.386)	–0.06 (–0.17 to 0.06; 0.318)	1.41 (0.05)	1.33 (0.07)
Total QALYs over 24 months (time discounted)	1.34 (0.06)	1.36 (0.04)	–0.03 (–0.17 to 0.12; 0.715)	–0.05 (–0.17 to 0.07; 0.385)	–0.06 (–0.17 to 0.06; 0.319)	1.38 (0.05)	1.31 (0.07)

SE, standard error.
a 95% CI estimated from imputed data sets using the 'mi estimate: regress' command in Stata.

Incremental cost-effectiveness results

The incremental cost-effectiveness results are presented in *Table 46* for the ITT and per-protocol analyses, with and without covariate adjustment. To illustrate the uncertainty around the point estimate for the ICER, *Figures 11–14* show 1000 bootstrapped cost and effect differences as a scatter plot on the cost-effectiveness plane.

When considering only the point estimate of the ICER, negative ICERs resulting from negative cost and positive effect differences (in the south-east quadrant of the cost-effectiveness plane) are indistinguishable from negative ICERs resulting from positive cost and negative effect differences (in the north-west quadrant); this is also the case for positive ICERs (north-east and south-west quadrants). As the uncertainty around the ICER for each of the four analyses (A–D) spans all four quadrants of the cost-effectiveness plane (more/less costly and more/less effective), CIs cannot be produced by taking the 25th and 975th value of the ranked bootstrapped ICER estimates. Instead, the graphs in *Figures 15–18* show cost-effectiveness acceptability curves, which plot the probability that arthroscopic repair is cost-effective compared with open repair at different levels of willingness to pay for health gains, ranging from £0 to £100,000 per QALY.

The uncertainty around the ICER is also presented in *Table 46* in terms of the probability that arthroscopic repair is more effective, less costly, dominant (more effective and less costly), dominated (less effective and more costly) and cost-effective at a willingness to pay of £20,000 per QALY compared with open repair.

Intention-to-treat analysis

For the base-case ITT analysis without adjustment for covariates, arthroscopic repair was less costly but less effective than open repair, resulting in a point estimate for the ICER of £30,001. This value represents the additional cost per QALY gained for open repair compared with arthroscopic repair. The probability of arthroscopic repair being less costly than open repair was 74% and the probability of arthroscopic repair being more effective than open repair was 48%.

When adjusting for covariates the probability of arthroscopic repair being more effective than open repair decreased to 23% and the probability of it being less costly decreased to 27%. The probability that arthroscopic repair was dominated by open repair in this analysis was 60%, compared with 16% in the unadjusted analysis. The probability of arthroscopic repair being cost-effective compared with open repair at a willingness to pay of £20,000 per QALY gained was 54% in the unadjusted analysis and 21% in the adjusted analysis.

Per-protocol analysis

In the per-protocol analysis, the point estimate for the ICER suggested that arthroscopic repair was both more costly and less effective in both the unadjusted and the adjusted analyses, meaning that it was dominated by open repair. Using the uncertainty results from the bootstrap replicates, the probability that arthroscopic repair is dominated by (more costly and less effective than) open repair was 55% in the unadjusted analysis and 63% in the adjusted analysis and the probability that arthroscopic repair is cost-effective compared with open repair at a willingness to pay of £20,000 per QALY gained was 30% in the unadjusted analysis and 19% in the adjusted analysis.

TABLE 46 Incremental analysis

Analysis	Total costs over 24 months (discounted) (£)[a]			Total QALYs over 24 months (discounted)[a]			ICER (quadrant) (£)[b]	Probability (%) that arthroscopic repair is				
	Arthroscopic, mean (SE)	Open, mean (SE)	Mean difference (95% CI)	Arthroscopic, mean (SE)	Open, mean (SE)	Mean difference (95% CI)		More effective	Less costly	Dominant	Dominated	Cost-effective at £20,000 per QALY gained
(A) Base case: ITT, no adjustment for covariates	2567 (176)	2699 (149)	–132 (–589 to 324; 0.569)	1.34 (0.04)	1.35 (0.04)	0.00 (–0.11 to 0.10; 0.935)	30,001 (SW)	47.5	74.4	37.5	15.6	53.7
(B) ITT, adjusted for covariates[c]	2567 (176)	2699 (149)	105 (–255 to 466; 0.565)	1.34 (0.04)	1.35 (0.04)	–0.04 (–0.12 to 0.05; 0.392)	Dominated (–2845; NW)	23.0	26.6	9.4	59.8	20.9
(C) Per protocol, no adjustment for covariates	3582 (223)	3360 (171)	222 (–328 to 773; 0.426)	1.34 (0.06)	1.36 (0.04)	–0.03 (–0.17 to 0.12; 0.715)	Dominated (–8272; NW)	36.5	19.2	9.9	55.1	30.0
(D) Per protocol, adjusted for covariates[c]	3582 (223)	3360 (171)	207 (–341 to 754; 0.456)	1.34 (0.06)	1.36 (0.04)	–0.06 (–0.17 to 0.06; 0.319)	Dominated (–3628; NW)	21.2	24.3	8.5	63.0	18.8

NW, north-west; SW, south-west.
a Uncertainty around costs and effects was calculated parametrically.
b Uncertainty around the ICER was estimated using 1000 bootstrap replicates of the final merged data set after multiple imputation.
c Covariates: EQ-5D at baseline (for QALY outcomes only), age, tear size and centre.

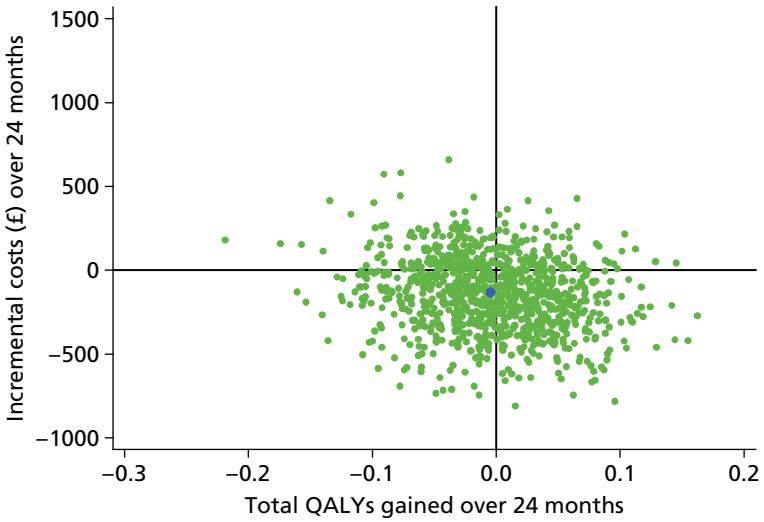

FIGURE 11 Cost-effectiveness plane, analysis A (base case: ITT, unadjusted).

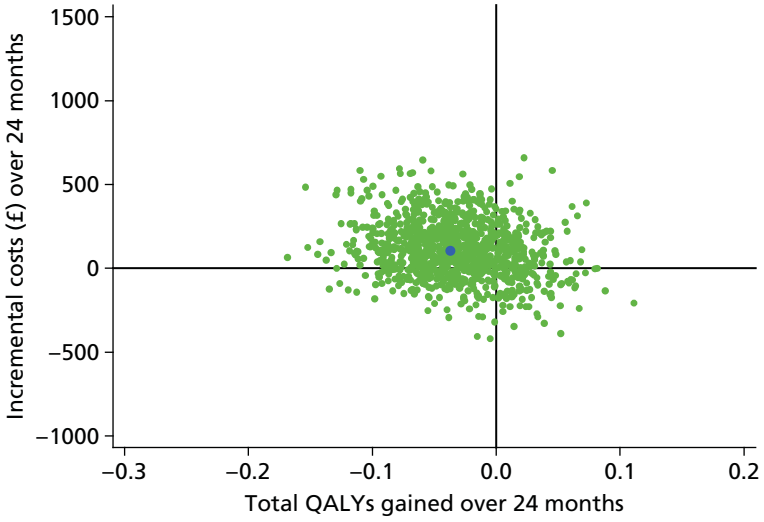

FIGURE 12 Cost-effectiveness plane, analysis B (ITT, adjusted).

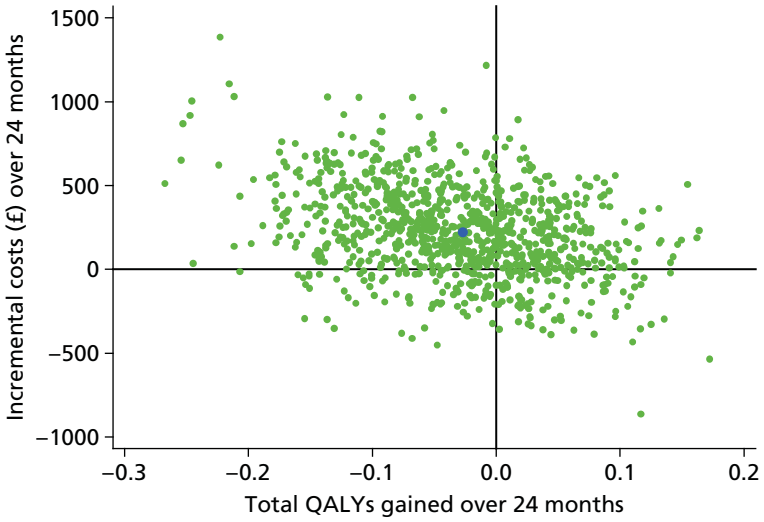

FIGURE 13 Cost-effectiveness plane, analysis C (per protocol, unadjusted).

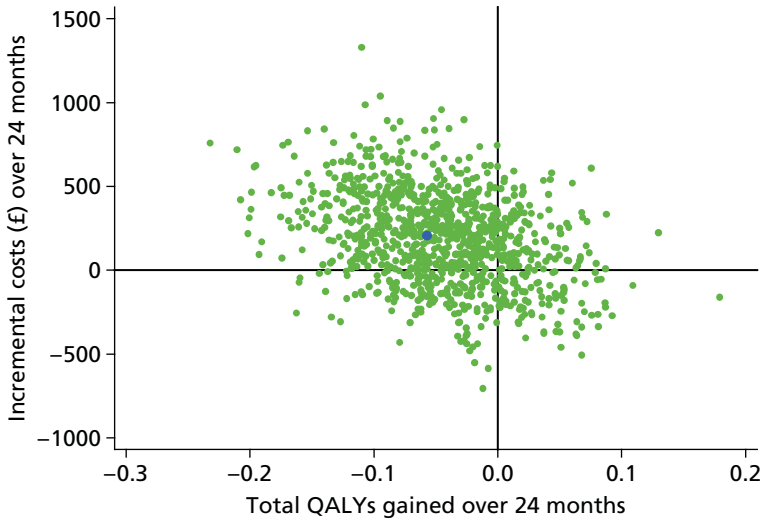

FIGURE 14 Cost-effectiveness plane, analysis D (per protocol, adjusted).

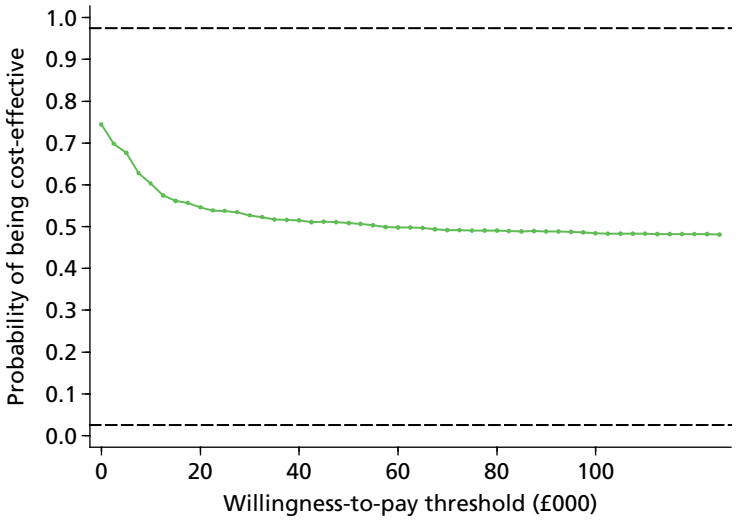

FIGURE 15 Cost-effectiveness acceptability curve, analysis A (base case: ITT, unadjusted). Dotted lines represent 95% CIs.

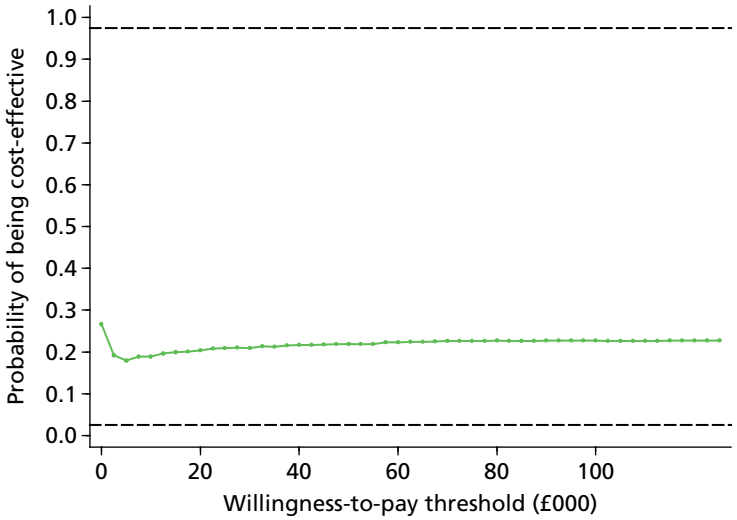

FIGURE 16 Cost-effectiveness acceptability curve, analysis B (ITT, adjusted). Dotted lines represent 95% CIs.

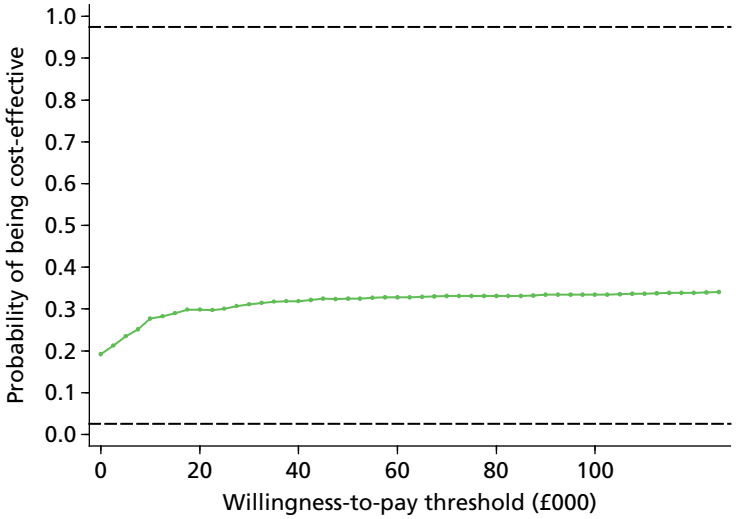

FIGURE 17 Cost-effectiveness acceptability curve, analysis C (per protocol, unadjusted). Dotted lines represent 95% CIs.

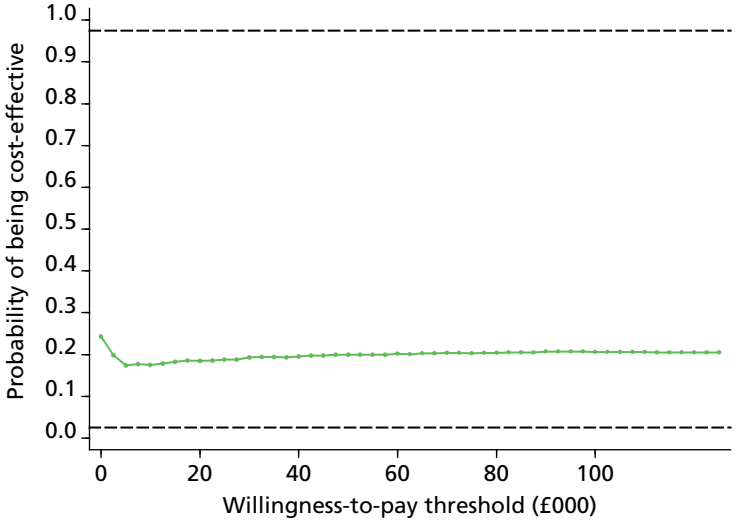

FIGURE 18 Cost-effectiveness acceptability curve, analysis D (per protocol, adjusted). Dotted lines represent 95% CIs.

Conclusion

For the ITT analysis there were no significant differences in mean costs between the arthroscopic repair group and the open repair group for any of the component resource-use categories, nor for the total follow-up costs at 12 months or 24 months. For the per-protocol analysis there was a significant difference in total initial procedure-related costs between the arthroscopic repair group and the open repair group, with arthroscopic repair being more costly by £371 (95% CI £135 to £607) with no covariate adjustment and £315 (95% CI £93 to £536) with covariate adjustment. The total cost of surgery alone (excluding nights in hospital) was also significantly different between the two groups, at £463 (95% CI £260 to £660) more costly for arthroscopic repair without covariate adjustment and £410 (95% CI £232 to £589) more costly for arthroscopic repair with covariate adjustment. Total QALYs accrued at 2 years averaged 1.34 (SE 0.04) in the arthroscopic group and 1.35 (SE 0.04) in the open repair group. The overall treatment cost at 2 years was £2567 (SE £176) for arthroscopic surgery and £2699 (SE £149) for open surgery, according to ITT analysis. This difference was not statistically significant.

For quality-of-life outcomes there was no statistically significant difference between the arthroscopic repair group and the open repair group, either for the ITT analysis or for the per-protocol analysis. The difference remained non-significant after adjusting for covariates.

In terms of incremental cost-effectiveness, arthroscopic repair was less costly but less effective than open repair in the ITT analysis, resulting in a point estimate for the ICER of £30,001 (without adjustment for covariates). The probability of arthroscopic repair being less costly than open repair was 74% and the probability of it being more effective than open repair was 48%. When adjusting for covariates, the probability of arthroscopic repair being more effective than open repair decreased to 23% and the probability of it being less costly decreased to 27%. For both the unadjusted and adjusted per-protocol analyses the point estimate for the ICER suggested that arthroscopic repair was both more costly and less effective, meaning that it was dominated by open repair.

Chapter 7 Discussion

The results of this RCT involving patients aged > 50 years with a symptomatic degenerative rotator cuff tear indicate that there are no significant differences in effectiveness, health-care costs or cost-effectiveness between arthroscopic repair and open repair. Both surgical techniques resulted in a significant improvement in the primary outcome, change in OSS between baseline and 2 years, and in all of the prespecified secondary outcome measures, which included the SPADI, the EQ-5D and the MHI-5. At 2 and 8 weeks post surgery an assessment was also carried out of analgesic use, return to activities and return to work. Patients improved from a baseline OSS of 25.7 to 41.5 at 24 months. All groups followed a similar pattern.

Response rates during follow-up

The protocol specified follow-up at times equivalent to 2 and 8 weeks after surgery. The success of this approach can be assessed in *Table 5*. Data were also collected through self-completed postal questionnaires, backed up by postal and telephone reminders and occasional completion of the questionnaire over the telephone. The standard rule in most trials is to time follow-up from randomisation. This was not appropriate for the early outcomes in this trial because of the variable time between randomisation and surgery. This variability occurred because of differences in NHS waiting times between centres. The overall response rates for the post-randomisation postal questionnaires were 408 out of 446 (91.5%) at 8 months, 406 out of 446 (91.0%) at 12 months and 389 out of 446 (87.2%) at 24 months. Response analysis showed that responders at 24 months had similar characteristics to non-responders.

Telephone questionnaires at 2 and 8 weeks post surgery

At 2 and 8 weeks there were no differences between groups for reported pain, levels of painkiller use or return to work. At 2 weeks, 131 out of 446 (29.4%) had no or mild pain, 232 out of 446 (52.0%) were taking painkillers and 80% of those in work were off sick. At 8 weeks 161 out of 446 (36.1%) had no or mild pain, 171 out of 446 (38.3%) were taking painkillers and 45% of those in work were off sick. These findings are broadly in line with advice given to patients before surgery.

Postal questionnaires at 8, 12 and 24 months

At 8 months, 77% of participants reported that their symptoms were much or slightly better; this had improved to 85% at 24 months, with no differences found between the groups. Operation time and time in theatre were both significantly lower (by approximately 12 minutes) in the open surgery group than in the arthroscopic group. The difference, however, was not observed in the non-randomised group. It may be the case that surgeons, when performing their preferred procedure, can undertake the procedures equally efficiently. One reason why we continued to follow-up the stratum B and stratum C participants after the rest-then-exercise arm was discontinued (see *Rest-then-exercise programme*) was to gather more information on surgical outcomes of the arthroscopic and open procedures. To that end we obtained data on another 142 surgical procedures from the non-randomised arms. Taken at face value it would appear that the procedures had a similar rate of complications and were safe.

Health economics

Follow-up at 24 months revealed no significant differences in costs or QALYs between arthroscopic and open treatment of rotator cuff tears (for either the ITT or the per-protocol analysis). There was no significant difference in time in theatre between arthroscopic and open surgery in the base-case ITT

analysis using multiple imputed data (see *Table 30*). The cost of surgery and the total overall procedure costs were significantly more for arthroscopic repair than for open repair in the per-protocol analysis but not in the ITT analysis (see *Table 33*). There was no significant difference in QALYs accruing to each group at 24 months, with a mean of 1.34 and 1.35 QALYs per patient for arthroscopic repair and open repair, respectively, in the base-case ITT analysis (see *Table 45*). There was also no significant different between the groups when the results were analysed per protocol. As a result, the incremental cost-effectiveness of arthroscopic repair compared with open repair is subject to a great deal of uncertainty. The probability that arthroscopic repair is cost-effective compared with open repair when the willingness to pay for health benefits is set at £20,000 per QALY was 54% in the base case (when not adjusting results for covariates) and only 21% when incorporating covariate adjustment (see *Table 46*).

Complications

The number of patients suffering significant complications was very low and less than the rate described by Moosmayer *et al.*,[60] but similar to that described by Kukkonen *et al.*[59] The infection rate in this study was 0.7% and the rate of revision surgery was 1.5%.

Cuff repair integrity at 12 months

During surgery, 72 out of 356 participants (20.2%) randomised to surgery and who underwent surgery were found not to have a tear (see *Table 11*). This rate of false-positive reporting of tears potentially indicates the relatively inaccurate diagnostic work-up of the participants. The majority (68%) of tears were diagnosed by ultrasound and the remainder by MRI (see *Table 6*). A Cochrane systematic review of the use of MRI, MRI arthrography and ultrasound for assessing rotator cuff tears in people for whom shoulder surgery is being considered analysed 20 studies.[79] For full-thickness tears they reported a sensitivity and specificity of 94% (95% CI 85% to 98%) and 93% (95% CI 83% to 97%), respectively, for MRI and 92% (95% CI 82% to 96%) and 93% (95% CI 81% to 97%), respectively, for ultrasound. These results do not seem to be reflected in the real-world setting of the NHS. At baseline, 321 out of 446 tears (72.0%) were classified as small/medium and 125 out of 446 tears (28.0%) were classified as large/massive, whereas at surgery 152 out of 330 tears (46.1%) were judged by the surgeon to be small/medium, 125 out of 330 tears (37.9%) were judged by the surgeon to be large/massive and 72 out of 356 participants (20.2%) were judged to have no tear (see *Table 11*). It is possible that tears had changed in size between the preoperative scan and surgery; however, it is more likely that these differences reflect inaccuracies in the interpretation of preoperative imaging. The operative findings should be used as the standard.[79]

In the randomised comparison, the mean difference in OSS at 2 years between healed tears and re-tears was 3 OSS points. The mean difference in OSS at 2 years between retears and unrepairable tears was also 3 OSS points. Healed repairs therefore fared best and unrepairable tears worst (see *Table 20*). A healed repair resulted in the greatest improvement in OSS. In the randomised group the OSS improved from 26.3 (SD 8.2) at baseline to 44.5 (SD 4.1) for the arthroscopic group and from 25.0 (SD 8.0) at baseline to 43.6 (SD 5.8) for the open group. The next best results were for the repaired tears that re-tore, which improved to 41.8 (SD 8.8) for the arthroscopic group and 40.8 (SD 7.6) for the open group. The worst results were seen for tears that were impossible to repair, which improved to 37.3 (SD 6.1) for the arthroscopic group and 35.1 (SD 9.7) for the open group. The results were similar for the non-randomised preference groups.

This improvement may be a result of the subacromial decompression surgery and tissue debridement that was invariably performed in these cases. Alternative reasons for the treatment effect include a period of rest after surgery, physiotherapy after surgery, spontaneous resolution or a placebo effect. It is clear that patients' symptoms can improve even after a protracted course, with 22 out of 81 participants (27.2%) who withdrew from the trial while on the waiting list for surgery also reporting resolution of symptoms (see *Table 10*).

Comparison with other randomised clinical trials

A Cochrane review of treatment for rotator cuff tears was published in 2008 in which no clear evidence in support of any particular intervention was reported.[16] A systematic review was conducted in May 2014 (see *Chapter 1*) and found one trial[53] of arthroscopic repair compared with mini-open repair in 100 patients published since the UKUFF trial started. Patients were followed for 1 year using the DASH questionnaire, with no treatment difference found for small and medium tears.[53] We found two further trials of surgery compared with conservative care published since the trial began. In the single-centre trial of small and medium tears by Moosmayer *et al.*,[60] the surgical group had better outcomes at 1 year. This study reported a full-thickness re-tear rate of 8% and a partial-thickness re-tear rate of 12%. In this study 14 out of 103 (13.6%) patients had previously received glucocorticoid injections, 49 out of 103 (47.6%) had received physiotherapy and the mean duration of symptoms was 9 and 12 months in the two groups, respectively. It would appear that, in this trial, patients were being advised to have surgery after a much shorter duration of symptoms and after a less comprehensive course of conservative therapies than is the case in the UK. In the Kukkonen *et al.*[59] study of small and medium tears the duration of symptoms was similar to that in this study at 26–28 months. Only 103 out of 167 (61.7%) had previously received conservative treatment in the form of cortisone injections. The waiting list for surgery in this Finnish study was < 4 weeks. There was no postoperative imaging and so repair integrity could not be assessed.

Strengths and weaknesses

This study was carried out in a large number of centres in the UK with wide geographical representation. Despite the length of time that has elapsed since the trial began, uncertainty still exists in the global surgical community regarding surgery for rotator cuff tear and the results of this trial are likely to influence care in the UK and globally.

Previous studies comparing surgery with conservative care have treated patients at an earlier stage with a shorter duration of symptoms and less, or no, previous experience of conservative care programmes, particularly physiotherapy and glucocorticoid injections. One reason why the original study design failed was that a high proportion of patients had already received and failed to respond to physiotherapy treatment (91.5%) and so it is not surprising that they were reluctant to pursue a further programme of conservative care.

Testing surgical interventions against non-operative treatments in a randomised trial is often challenging. This is particularly the case for chronic conditions with indolent onset that cause pain and reduce quality of life. If patients are recruited at the conventional stage of the treatment pathway they will invariably have already received conservative care (as was the case with this study). We involved patients during both the design and the conduct of the trial. The consistent feedback was that patients would be reluctant to try more conventional conservative care. For this reason experienced physiotherapy leaders within BESS designed the rest-then-exercise programme as a novel conservative programme that could be delivered to patients across the UK. An important consideration was the wide variation in conservative care programmes across the UK and the absence of standardisation of physiotherapy treatments. The rest-then-exercise programme was designed so that it could be delivered remotely and in the same way to all patients. We did consider the option of bringing surgery forward in the treatment pathway to try and recruit patients who had not yet received physiotherapy but this was not supported by either our patient representatives or our independent surgical advisers.

A second reason for crossover was that patients in the non-operative arm were put on the waiting list for surgery at the time of randomisation. At the time the trial was commissioned and designed NHS waiting lists for this type of surgery were > 12 months on average. This design was proposed in an attempt to improve recruitment by not disadvantaging patients randomised to the conservative arm who subsequently needed surgery in the belief that with 12 months on the waiting list the conservative programme could be

evaluated fairly. Feedback from patient representatives during the study design process was that patients would not agree to participate in the rest-then-exercise programme if they were not also put on the NHS waiting list. During the course of the trial the introduction of waiting list targets reduced waiting times in the NHS and this adversely affected the trial.

The rate of withdrawal from the planned surgery was 81 out 446 (18.2%) for the surgical groups. We believe that this is likely to be a real NHS phenomenon. The reasons for withdrawal were not different between the groups and included the patient becoming asymptomatic and the development of other medical conditions that prevented surgery taking place (see *Table 10*). It is important to note that the levels of withdrawal were equal in all groups, including the non-randomised groups.

The reasons why patients did not receive a surgical repair were because no tear was found (scan false positive) or because the tear was impossible to repair. The relative inaccuracy of preoperative scanning in a real-world NHS setting compared with the accuracy reported in the literature is worthy of further investigation.

We have considered these issues further in the design of the CSAW (Can Shoulder Arthroscopy Work) trial [see https://clinicaltrials.gov/ct2/show/NCT01623011 (accessed 25 August 2015)], which has also been led from Oxford with the same chief investigator. This trial uses the same network of shoulder surgeons and centres and compares arthroscopic subacromial decompression with placebo surgery and active monitoring in patients with subacromial shoulder pain but no rotator cuff tear. It has successfully completed recruitment of 300 patients without any significant crossover between the randomised groups. Various factors have contributed to the success of this trial compared with the UKUFF trial. First, the trial works within accepted patient pathways and does not attempt to offer to patients treatments that have already been tried and which have failed to result in improvement, nor does it offer surgical treatment too early; all patients in the CSAW trial had a minimum duration of symptoms and had received well-delivered conservative care. In the CSAW trial 30 surgeons were involved in recruiting participants, all of whom were provided with instruction in recruiting before the trial and feedback from site visits during the trial. This feedback included the recording of patient consultations with advice about how individual surgeons might improve recruitment.

Patient and public involvement and engagement

Patients were involved in the interpretation of the trial findings and in the preparation of the monograph through patient representation on the TSC. The results were discussed with patient groups associated with BESS and with priority-setting forums, including the James Lind Alliance.

Generalisability of the results

We designed the trial with the aim of making the management policies as similar as possible to normal NHS care. In the first configuration the trial involved 47 centres and then, after the rest-then-exercise programme was closed, 19 centres. The centres were widely dispersed across the UK and included teaching hospitals and district general hospitals. Recruitment was performed by surgeons and surgeons chose the specific aspects of the procedure once a patient had been allocated to either arthroscopic repair or open repair. There was no requirement for extra tests or hospital visits and simple entry criteria identified people eligible for the study. The results should therefore be easily generalisable to standard NHS care. No single centre recruited > 10% of the total patients, which significantly enhances the generalisability of the results. All participating surgeons had been trained in the techniques, had undergone at least 2 years of independent practice as a consultant surgeon and undertook a minimum of five rotator cuff repair operations per annum.

Rest-then-exercise programme

The rest-then-exercise programme was designed by a group of leading shoulder physiotherapists representing the physiotherapy section of BESS. All members of the group had considerable experience in the non-operative management of patients with shoulder pain and with rotator cuff tears in particular. The programme was designed to be delivered remotely using an information booklet and CD, with access to physiotherapy guidance on a free telephone line. The same programme was provided to patients recruited to all 47 centres participating in the trial. All patients were provided with a sling, which they were advised to wear for up to 4 weeks with the aim of reducing pain levels to, or below, 4/10 on a VAS. In addition to information regarding rotator cuff tears (e.g. lack of correlation between pain and structure), a variety of exercises were detailed with advice to perform them for a further 6–12 weeks.

As described in the approved grant application and required by the ethics committee, patients in the rest-then-exercise arm were put on the NHS waiting list to prevent disadvantaging them should the rest-then-exercise programme fail to adequately resolve their symptoms. When the trial was designed NHS waiting lists were around 12 months, giving more than sufficient time to determine whether the conservative programme was effective. During the course of the study additional funding was made available to the NHS and waiting lists shortened to an average of 2–4 months, which may have played a part in the problems encountered with the rest-then-exercise programme.

Because of the reconfiguration of the trial, data from participants allocated to the rest-then-exercise arm of the original UKUFF study no longer contribute to the formal comparisons being reported within this monograph. However, it is important to record the details of all patients randomised across the totality of the study for completeness and transparency of reporting (but also in accordance with the expectation provided to participants as part of the consent process).

The outcomes of those allocated to rest then exercise were presented in *Table 23*. In total, 77 of the 214 participants (36%) did not complete the 10-week course of treatment and progressed to surgery (see *Table 24*), 88 (41%) completed the course before progressing to surgery (see *Table 25*) and 36 (17%) completed the full course and did not have surgery (see *Table 26*). A further 14 patients withdrew. As this component of the trial was stopped, no formal comparisons can be or have been made. All patients appeared to improve but it is not possible to determine why improvements were made. The number of patients previously having received non-operative care (including physiotherapy and cortisone injections) was high [604/660 (91.5%)]. In total, 401 out of 660 (60.8%) had received a cortisone injection in the last 5 years, 414 out of 660 (62.7%) had received physiotherapy and 87 out of 660 (13.2%) had received any other treatment. Of those randomised to rest then exercise, 141 out of 214 (65.9%) had received physiotherapy, 129 out of 214 (60.3%) had received a cortisone injection and 20 out of 214 (9.3%) had received some other treatment, such as acupuncture. Only 19 out of 214 (8.9%) patients randomised to rest then exercise [56/660 (8.5%) of the total trial participants] had not received treatment prior to randomisation. The mean duration of symptoms at baseline is shown in *Table 7* and ranged from 2.0 to 2.7 years across the groups, with no significant differences between them.

Data across all subgroups show that participants' assessments of their disease-specific and generic quality-of-life scores improved markedly from baseline to final outcomes. However, because of the sizeable rates of surgical intervention in this cohort of participants, it is difficult to dissect the specific gains that could be attributed to the rest-then-exercise programme and to surgery.

Chapter 8 Conclusion

In patients aged > 50 years with a degenerative rotator cuff tear there were no significant differences in the primary outcome (OSS) and all other prespecified secondary outcomes between open repair and arthroscopic repair at 2 years. Rotator cuff surgery resulted in a significant improvement in symptoms (OSS 25.7/48 at baseline to 41.5/48 at 2 years). Improvement occurred despite the relatively small number of patients who underwent a rotator cuff repair. Patients who had an unrepairable tear at surgery and those in whom the repair subsequently re-tore also improved from baseline.

In total, 1.34 (SE 0.04) QALYs accrued at 2 years in the arthroscopic repair group and 1.35 (SE 0.04) QALYs accrued at 2 years in the open repair group, whereas the overall treatment cost at 2 years was £2567 (SE £176) for arthroscopic surgery and £2699 (SE £149) for open surgery, according to ITT analysis; neither cost nor QALY differences were statistically significant.

The incidence of complications and serious adverse events was low, with only 0.7% of deep infections and 1.5% of revision repair operations.

Only 162 out of 273 (59%) patients randomised to surgery underwent a rotator cuff repair. In total, 59 out of 273 (22%) patients withdrew while on the waiting list. The most common reasons for this were improvement in symptoms and the development of another medical condition. A total of 52 out of 273 (19%) patients underwent subacromial decompression and no rotator cuff repair. The most common reasons for this were that no tear was found or that the tear was impossible to repair. The best outcome was seen in patients in whom the repair had healed; strategies to improve tendon healing are likely to improve outcomes for all tear sizes and ages. This was followed by a repair that subsequently re-tore. The worst outcome was seen in patients whose tear was unrepairable at surgery. Re-tears were found in 93 out of 233 (40%) patients who underwent repair surgery, with no difference between the open and arthroscopic groups. Re-tears occurred after repairs to all tear sizes and the risk of re-tear was not influenced by age. Previous studies have been small and either single-centre or in a small number of centres and have not had the same generalisability as this trial.

It proved impossible to test a rest-then-exercise programme in the context of a pragmatic trial in the 47 centres during routine NHS care. In total, 91.5% of patients randomised had previously received conservative care and the mean duration of symptoms was 2.5 years.

Implications for health care

Clinical

i. Suitably selected patients can benefit equally well from either open or arthroscopic rotator cuff repair with a low risk of complications.
ii. In the subset of patients for whom repair was possible the greatest benefit is seen in patients in whom the rotator cuff repair is successful and remains intact.
iii. A significant improvement was seen in all randomised and non-randomised groups, including in those in whom a repair was not possible or in whom there was a postoperative re-tear, suggesting that there are other treatment effects.
iv. No evidence of an effect of age or tear size on outcome was found.

Health economics

i. There is no significant cost difference at 2 years between open and arthroscopic rotator cuff repair.
ii. Per protocol the costs of arthroscopic surgery are significantly greater than the costs of open surgery. This is largely because of the longer operating time for arthroscopic surgery.

Recommendations for future research

Clinical

i. There is a case to continue follow-up of the patients who underwent surgery and who had a repair that healed, who had a repair that re-tore, who had a tear that was impossible to repair or who had no tear. There is early evidence at 2 years' follow-up that these groups have different outcomes. This unique study cohort provides the opportunity to determine the longer-term consequences of rotator cuff tear and repair.
ii. There is a need to explore the basis of the treatment effect seen with a RCT of rotator cuff repair compared with placebo surgery.

Health economics

i. With enforced restrictions on surgical training time there is also a need to understand both the costs and the time required for surgeons to learn arthroscopy and open surgery, including the volume of cases that needs to be performed to maintain skills. If the time required for training and maintaining either arthroscopic or open skills differs then this will have cost implications for surgical training programmes and workforce planning.
ii. There is a need to evaluate cost-effectiveness over a longer period than 24 months using further follow-up data from this study and elsewhere on the longer-term consequences of rotator cuff tear and repair.

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Andrew J Carr (Nuffield Professor of Orthopaedics, Head of Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford) was the principal grant applicant and contributed to the development of the trial protocol and the preparation of the report and was responsible overall for the conduct of the trial.

Cushla D Cooper (Trial Co-ordinator, Oxford) contributed to the development of the trial protocol and was responsible for the daily management and conduct of the trial throughout and contributed to the preparation of the report.

Marion K Campbell (Grant Holder, Director of Health Services Research Unit, University of Aberdeen) contributed to the grant application and the trial design, commented on all aspects of the conduct of the trial and contributed to the preparation of the report.

Jonathan L Rees (Grant Holder, Consultant Orthopaedic Surgeon) contributed to the grant application and the trial design and the preparation of the report.

Jane Moser (Grant Holder, Consultant Shoulder Physiotherapist) contributed to the grant application and the trial design, led the development of the non-operative comparator and contributed to the preparation of the report.

David J Beard (Grant Holder, Professor of Musculoskeletal Sciences), contributed to the grant application and the trial design and the preparation of the report.

Ray Fitzpatrick (Grant Holder, Professor of Public Health) contributed to the grant application and the trial design and the preparation of the report.

Alastair Gray (Grant Holder, Professor of Health Economics) was responsible for the economic evaluation section of the grant application and protocol and contributed to the preparation of the report.

Jill Dawson (Grant Holder, Senior Research Scientist and University Research Lecturer) contributed to the grant application and the trial design and the preparation of the report.

Jacqueline Murphy (Research Fellow, Health Economics) conducted the analysis of the economic models for the report and contributed to the preparation of the report.

Hanne Bruhn (Trial Manager, Aberdeen) was responsible for the oversight of data collection and contributed to the preparation of the final report.

David Cooper (Statistician) conducted the statistical analysis and data cleaning and contributed to the preparation of the report.

Craig R Ramsay (Grant Holder, Professor of Health Technology Assessment) contributed to the grant application and the trial design, oversaw the statistical analysis and contributed to the preparation of the report.

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Data-sharing statement

Data can be obtained from the corresponding author.

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Appendix 1 Per-protocol data tables

TABLE 47 Assessment data

Assessment	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Size of tear				
Small/medium	49 (77.8)	66 (77.6)	23 (46.0)	28 (70.0)
Large/massive	14 (22.2)	19 (22.4)	27 (54.0)	12 (30.0)
Method of diagnosing tear				
MRI	18 (28.6)	22 (25.9)	9 (18.0)	11 (27.5)
Ultrasound	43 (68.3)	56 (65.9)	36 (72.0)	27 (67.5)
Missing	2 (3.2)	7 (8.2)	5 (10.0)	2 (5.0)
Received physiotherapy on affected shoulder in the last 5 years				
Yes	35 (55.6)	54 (63.5)	34 (68.0)	29 (72.5)
No	19 (30.2)	24 (28.2)	11 (22.0)	4 (10.0)
Missing	9 (14.3)	7 (8.2)	5 (10.0)	7 (17.5)
Duration of physiotherapy (weeks)				
≤ 4	8 (22.9)	11 (20.4)	3 (8.8)	7 (24.1)
5–12	12 (34.3)	14 (25.9)	11 (32.4)	10 (34.5)
> 12	5 (14.3)	17 (31.5)	14 (41.2)	7 (24.1)
Missing	10 (28.6)	12 (22.2)	6 (17.6)	5 (17.2)
Received an injection in affected shoulder in the last 5 years				
Yes	35 (55.6)	52 (61.2)	31 (62.0)	26 (65.0)
No	23 (36.5)	22 (25.9)	13 (26.0)	7 (17.5)
Missing	5 (7.9)	11 (12.9)	6 (12.0)	7 (17.5)
Number of injections				
1	14 (40.0)	20 (38.5)	13 (41.9)	11 (42.3)
2	10 (28.6)	17 (32.7)	10 (32.3)	7 (26.9)
3	1 (2.9)	8 (15.4)	6 (19.4)	7 (26.9)
4	2 (5.7)	1 (1.9)		
5	2 (5.7)	1 (1.9)		
6	1 (2.9)	2 (3.8)		
7				
9				1 (3.8)
10			1 (3.2)	
Missing	5 (14.3)	3 (5.8)	1 (3.2)	

continued

TABLE 47 Assessment data (*continued*)

Assessment	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Received other treatment on the affected shoulder in the last 5 years				
Yes	7 (11.1)	19 (22.4)	2 (4.0)	7 (17.5)
No	33 (52.4)	41 (48.2)	28 (56.0)	15 (37.5)
Missing	23 (36.5)	25 (29.4)	20 (40.0)	18 (45.0)
Other treatment				
Acupuncture	1 (14.3)	3 (15.8)	1 (50.0)	3 (42.9)
Analgesics	2 (28.6)	9 (47.4)		1 (14.3)
Chiropractor	1 (14.3)	2 (10.5)		1 (14.3)
Exercises		1 (5.3)		
Massage				1 (14.3)
Osteopathy		1 (5.3)		1 (14.3)
TENS	1 (14.3)			
Ultrasound		1 (5.3)		
Missing	2 (28.6)	2 (10.5)	1 (50.0)	
Received no previous treatment on shoulder in the last 5 years	9 (14.3)	5 (5.9)	6 (12.0)	2 (5.0)
Are there any problems with patient's other shoulder?				
No problems	41 (65.1)	51 (60.0)	27 (54.0)	23 (57.5)
Mild problems	12 (19.0)	21 (24.7)	14 (28.0)	10 (25.0)
Moderate problems	6 (9.5)	7 (8.2)	7 (14.0)	6 (15.0)
Severe problems	2 (3.2)	3 (3.5)	1 (2.0)	1 (2.5)
Missing	2 (3.2)	3 (3.5)	1 (2.0)	

TENS, transcutaneous electrical nerve stimulation.

TABLE 48 Baseline data

Characteristic	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Age (years), *n*, mean (SD)	63, 61.7 (6.5)	85, 62.2 (7.3)	50, 65.3 (6.7)	40, 61.1 (6.2)
Years with shoulder problem, *n*, mean (SD)	63, 2.8 (4.6)	85, 2.6 (4.9)	49, 2.5 (3.3)	40, 3.3 (6.3)
OSS, *n*, mean (SD)	63, 25.6 (8.4)	85, 24.6 (7.8)	50, 25.5 (8.5)	40, 24.8 (7.7)
SPADI, *n*, mean (SD)	63, 63.7 (22.7)	85, 62.8 (21.6)	50, 61.5 (22.9)	40, 64.6 (17.7)
SPADI pain, *n*, mean (SD)	63, 71.2 (19.9)	85, 71.7 (19.6)	50, 72.1 (21.4)	40, 74.6 (17.1)
SPADI disability, *n*, mean (SD)	63, 59.0 (25.8)	84, 57.4 (24.8)	50, 54.9 (26.2)	40, 58.4 (20.1)
MHI-5, *n*, mean (SD)	63, 21.9 (5.0)	85, 22.8 (4.5)	49, 22.9 (5.1)	40, 22.3 (4.7)
EQ-5D, *n*, mean (SD)	62, 0.529 (0.315)	84, 0.509 (0.285)	50, 0.505 (0.320)	39, 0.472 (0.306)
Sex				
Male	36 (57.1)	55 (64.7)	33 (66.0)	26 (65.0)
Female	27 (42.9)	30 (35.3)	16 (32.0)	14 (35.0)
Missing			1 (2.0)	
Highest qualification				
None	26 (41.3)	34 (40.0)	22 (44.0)	20 (50.0)
Secondary	21 (33.3)	33 (38.8)	21 (42.0)	9 (22.5)
Higher	16 (25.4)	17 (20.0)	5 (10.0)	11 (27.5)
Missing		1 (1.2)	2 (4.0)	
Housing tenure				
Home owner	49 (77.8)	76 (89.4)	46 (92.0)	35 (87.5)
Private rent	4 (6.3)			1 (2.5)
Council rent	7 (11.1)	3 (3.5)	4 (8.0)	3 (7.5)
Other	3 (4.8)	6 (7.1)		1 (2.5)
Lives alone				
Yes	13 (20.6)	6 (7.1)	7 (14.0)	5 (12.5)
No	46 (73.0)	73 (85.9)	42 (84.0)	34 (85.0)
Missing	4 (6.3)	6 (7.1)	1 (2.0)	1 (2.5)
Employment status				
Full-time	22 (34.9)	36 (42.4)	15 (30.0)	17 (42.5)
Part-time	10 (15.9)	12 (14.1)	10 (20.0)	6 (15.0)
Homemaker	2 (3.2)	4 (4.7)		1 (2.5)
Retired	26 (41.3)	29 (34.1)	25 (50.0)	15 (37.5)
Unemployed	3 (4.8)	3 (3.5)		1 (2.5)
Missing		1 (1.2)		

continued

TABLE 48 Baseline data (*continued*)

Characteristic	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Type of work				
Manual	17 (53.1)	30 (62.5)	17 (68.0)	14 (60.9)
Non-manual	13 (40.6)	15 (31.3)	8 (32.0)	9 (39.1)
Not sure	2 (6.3)	2 (4.2)		
Missing		1 (2.1)		
Off sick or working reduced duties				
Yes, off sick	2 (6.3)	6 (12.5)	2 (8.0)	1 (4.3)
Yes, working reduced duties	6 (18.8)	5 (10.4)	5 (20.0)	5 (21.7)
No, working usual duties	22 (68.8)	36 (75.0)	18 (72.0)	17 (73.9)
Missing	2 (6.3)	1 (2.1)		
Handedness				
Right-handed	57 (90.5)	76 (89.4)	48 (96.0)	33 (82.5)
Left-handed	3 (4.8)	6 (7.1)	2 (4.0)	5 (12.5)
Both	3 (4.8)	3 (3.5)		2 (5.0)
Would you be able to do your job or everyday activities with arm in a sling?				
No	38 (60.3)	55 (64.7)	29 (58.0)	21 (52.5)
Yes, with difficulty	25 (39.7)	30 (35.3)	21 (42.0)	19 (47.5)

TABLE 49 Operative details

Operative detail	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Procedure side				
Left	26 (41.3)	26 (30.6)	11 (22.0)	12 (30.0)
Right	37 (58.7)	59 (69.4)	39 (78.0)	28 (70.0)
Missing				
Ease of repair				
Easy	18 (28.6)	39 (45.9)	12 (24.0)	11 (27.5)
Moderate	28 (44.4)	25 (29.4)	19 (38.0)	12 (30.0)
Difficult	12 (19.0)	12 (14.1)	11 (22.0)	11 (27.5)
Impossible		2 (2.4)	1 (2.0)	2 (5.0)
Missing	5 (7.9)	7 (8.2)	7 (14.0)	4 (10.0)
Size of tear				
Small	22 (34.9)	25 (29.4)	11 (22.0)	6 (15.0)
Medium	25 (39.7)	32 (37.6)	10 (20.0)	11 (27.5)
Large	10 (15.9)	18 (21.2)	16 (32.0)	13 (32.5)
Massive	5 (7.9)	9 (10.6)	13 (26.0)	10 (25.0)
Missing	1 (1.6)	1 (1.2)		
Surgical opinion of completeness of repair				
Poor	6 (9.5)	6 (7.1)	4 (8.0)	5 (12.5)
Good	37 (58.7)	42 (49.4)	29 (58.0)	20 (50.0)
Excellent	16 (25.4)	33 (38.8)	9 (18.0)	11 (27.5)
Missing	4 (6.3)	4 (4.7)	8 (16.0)	4 (10.0)
Total minutes in theatre, *n*, mean (SD)	48, 107.5 (33.3)	74, 87.8 (30.1)	32, 99.2 (25.8)	30, 99.9 (52.6)
Operation time, *n*, mean (SD)	48, 76.4 (30.5)	72, 58.1 (22.8)	24, 70.4 (23.5)	25, 75.4 (38.3)

TABLE 50 Intraoperative complications

Complication	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Intraoperative problem				
Anaesthetic		1 (1.2)		
Equipment	3 (4.8)	1 (1.2)	2 (4.0)	
Implant		1 (1.2)	1 (2.0)	
Surgical	5 (7.9)	1 (1.2)	3 (6.0)	
Other	2 (3.2)	4 (4.7)	3 (6.0)	2 (5.0)
Staff problems				2 (5.0)
Any intraoperative problems	7 (11.1)	6 (7.1)	2 (4.0)	7 (14.0)
Did the procedure change as a result of an intraoperative problem?				
Yes			2 (28.6)	
No	7 (100.0)	4 (66.7)	4 (57.1)	2 (100.0)
Unsure			1 (14.3)	
Missing		2 (33.3)		

TABLE 51 Two-week follow-up

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Completed follow-up forms	56 (88.9)	77 (90.6)	42 (84.0)	36 (90.0)
Within the last 24 hours, have you been wearing a sling at all?				
Yes	49 (87.5)	64 (83.1)	40 (95.2)	32 (88.9)
No	6 (10.7)	12 (15.6)	2 (4.8)	4 (11.1)
Missing	1 (1.8)	1 (1.3)		
If yes, how long have you worn the sling for?				
> 12 hours	45 (91.8)	61 (95.3)	36 (90.0)	23 (71.9)
> 6 hours but < 12 hours	3 (6.1)	2 (3.1)	1 (2.5)	6 (18.8)
> 3 hours but < 6 hours	1 (2.0)		1 (2.5)	1 (3.1)
< 3 hours		1 (1.6)		
Missing			2 (5.0)	2 (6.3)
Within the last 24 hours, how would you describe the worst pain from your shoulder?				
None	4 (7.1)	3 (3.9)	2 (4.8)	2 (5.6)
Mild	16 (28.6)	19 (24.7)	13 (31.0)	12 (33.3)
Moderate	22 (39.3)	38 (49.4)	17 (40.5)	17 (47.2)
Severe	11 (19.6)	15 (19.5)	8 (19.0)	5 (13.9)
Unbearable	2 (3.6)	1 (1.3)	2 (4.8)	
Missing	1 (1.8)	1 (1.3)		
Within the last 24 hours, how much has pain from your shoulder interfered with your usual work?				
Not at all	9 (16.1)	7 (9.1)	9 (21.4)	7 (19.4)
A little bit	6 (10.7)	8 (10.4)	7 (16.7)	6 (16.7)
Moderately	14 (25.0)	26 (33.8)	7 (16.7)	7 (19.4)
Greatly	16 (28.6)	22 (28.6)	7 (16.7)	11 (30.6)
Totally	10 (17.9)	13 (16.9)	12 (28.6)	5 (13.9)
Missing	1 (1.8)	1 (1.3)		
Were you troubled by pain from your shoulder in bed last night?				
No, not at all	14 (25.0)	13 (16.9)	8 (19.0)	10 (27.8)
Yes, just at first	5 (8.9)	5 (6.5)	4 (9.5)	
Yes, during some of the night	25 (44.6)	28 (36.4)	19 (45.2)	14 (38.9)
Yes, throughout the night	11 (19.6)	30 (39.0)	11 (26.2)	12 (33.3)
Missing	1 (1.8)	1 (1.3)		
Within the last 24 hours, have you taken any painkillers because of your shoulder?				
Yes	40 (71.4)	56 (72.7)	31 (73.8)	28 (77.8)
No	15 (26.8)	20 (26.0)	11 (26.2)	8 (22.2)
Missing	1 (1.8)	1 (1.3)		

continued

TABLE 51 Two-week follow-up (*continued*)

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
If yes, how many painkillers have you taken in the last 24 hours?				
1	18 (45.0)	25 (44.6)	15 (48.4)	14 (50.0)
2	15 (37.5)	25 (44.6)	11 (35.5)	8 (28.6)
3	5 (12.5)	3 (5.4)	5 (16.1)	3 (10.7)
4		1 (1.8)		2 (7.1)
5	1 (2.5)	1 (1.8)		1 (3.6)
Missing	1 (2.5)	1 (1.8)		
During the (last 2 weeks) time since the completion of surgery or rest then exercise, have you received any additional treatment on your shoulder?				
Yes	3 (5.4)	14 (18.2)	5 (11.9)	2 (5.6)
No	50 (89.3)	60 (77.9)	36 (85.7)	32 (88.9)
Missing	3 (5.4)	3 (3.9)	1 (2.4)	2 (5.6)
If yes, what was the additional treatment?				
Injection				
Antibiotics		1 (7.1)		
Physiotherapy	1 (33.3)	2 (14.3)	2 (40.0)	1 (50.0)
Wound or dressing		5 (35.7)	2 (40.0)	
Not for shoulder problem	1 (33.3)	1 (7.1)		1 (50.0)
Pain relief	1 (33.3)	5 (35.7)	1 (20.0)	
Are you currently employed?				
Yes	28 (50.0)	40 (51.9)	22 (52.4)	24 (66.7)
No	27 (48.2)	36 (46.8)	20 (47.6)	12 (33.3)
Missing	1 (1.8)	1 (1.3)		
If employed, are you currently off sick or working reduced duties because of your shoulder?				
Yes, off sick	24 (85.7)	36 (90.0)	18 (81.8)	19 (79.2)
Yes, working reduced duties	3 (10.7)	2 (5.0)	3 (13.6)	4 (16.7)
No, working usual hours/duties	1 (3.6)	2 (5.0)	1 (4.5)	
Missing				1 (4.2)

TABLE 52 Eight-week follow-up

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Completed follow-up forms	55 (87.3)	78 (91.8)	41 (82.0)	32 (80.0)
Within the last 24 hours, have you been wearing a sling at all?				
Yes	5 (9.1)	13 (16.7)	5 (12.2)	6 (18.8)
No	50 (90.9)	65 (83.3)	36 (87.8)	26 (81.3)
If yes, how long have you worn the sling for?				
> 12 hours	1 (20.0)	3 (23.1)	2 (40.0)	1 (16.7)
> 6 hours but < 12 hours		4 (30.8)		1 (16.7)
> 3 hours but < 6 hours	1 (20.0)	6 (46.2)	1 (20.0)	1 (16.7)
< 3 hours	3 (60.0)		2 (40.0)	1 (16.7)
Missing				2 (33.3)
Within the last 24 hours, how would you describe the worst pain you have had from your shoulder?				
None	4 (7.3)	6 (7.7)	3 (7.3)	3 (9.4)
Mild	26 (47.3)	38 (48.7)	13 (31.7)	12 (37.5)
Moderate	18 (32.7)	19 (24.4)	16 (39.0)	11 (34.4)
Severe	7 (12.7)	14 (17.9)	9 (22.0)	6 (18.8)
Unbearable		1 (1.3)		
Within the last 24 hours, how much has pain from your shoulder interfered with your usual work?				
Not at all	16 (29.1)	13 (16.7)	8 (19.5)	7 (21.9)
A little bit	15 (27.3)	23 (29.5)	14 (34.1)	10 (31.3)
Moderately	17 (30.9)	27 (34.6)	11 (26.8)	9 (28.1)
Greatly	5 (9.1)	12 (15.4)	6 (14.6)	5 (15.6)
Totally	2 (3.6)	3 (3.8)	2 (4.9)	1 (3.1)
Were you troubled by pain from your shoulder in bed last night?				
No, not at all	24 (43.6)	25 (32.1)	14 (34.1)	10 (31.3)
Yes, just at first	3 (5.5)	5 (6.4)	4 (9.8)	1 (3.1)
Yes, during some of the night	19 (34.5)	27 (34.6)	16 (39.0)	13 (40.6)
Yes, throughout the night	9 (16.4)	21 (26.9)	7 (17.1)	8 (25.0)
Within the last 24 hours, have you taken any painkillers for your shoulder?				
Yes	28 (50.9)	44 (56.4)	23 (56.1)	20 (62.5)
No	27 (49.1)	34 (43.6)	18 (43.9)	12 (37.5)
If yes, how many painkillers have you taken?				
1	19 (67.9)	26 (59.1)	12 (52.2)	8 (40.0)
2	7 (25.0)	15 (34.1)	6 (26.1)	4 (20.0)
3	1 (3.6)	3 (6.8)	2 (8.7)	1 (5.0)
4	1 (3.6)			1 (5.0)
Missing			3 (13.0)	6 (30.0)

continued

TABLE 52 Eight-week follow-up (*continued*)

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
During the time (last 6 weeks) since we spoke to you last, have you had any additional treatment for your shoulder?				
Yes	5 (9.1)	8 (10.3)	3 (7.3)	5 (15.6)
No	47 (85.5)	69 (88.5)	38 (92.7)	27 (84.4)
Missing	3 (5.5)	1 (1.3)		
If yes, what additional treatment did you receive?				
Injection		1 (12.5)		
Antibiotics		2 (25.0)		1 (20.0)
Physiotherapy	5 (100.0)	2 (25.0)	2 (66.7)	4 (80.0)
Wound or dressing		1 (12.5)		
Hospital admission			1 (33.3)	
Surgery and antibiotics		2 (25.0)		
Are you currently employed?				
Yes	28 (50.9)	42 (53.8)	17 (41.5)	18 (56.3)
No	27 (49.1)	35 (44.9)	22 (53.7)	13 (40.6)
Missing		1 (1.3)	2 (4.9)	1 (3.1)
If yes, are you currently off sick or working reduced hours because of your shoulder?				
Yes, off sick	13 (46.4)	23 (54.8)	11 (64.7)	11 (61.1)
Yes, working reduced duties	7 (25.0)	10 (23.8)	4 (23.5)	3 (16.7)
No, working usual hours/duties	8 (28.6)	8 (19.0)	2 (11.8)	4 (22.2)
Missing		1 (2.4)		

TABLE 53 Symptoms at 8, 12 and 24 months

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
8-month follow-up forms completed	60 (95.2)	82 (96.5)	50 (100.0)	38 (95.0)
12-month follow-up forms completed	62 (98.4)	83 (97.7)	47 (94.0)	38 (95.0)
24-month follow-up forms completed	58 (92.1)	81 (95.3)	45 (90.0)	36 (90.0)
How are the problems related to your shoulder now compared with 8 months ago?				
Much better	40 (66.7)	55 (67.1)	34 (68.0)	23 (60.5)
Slightly better	12 (20.0)	11 (13.4)	11 (22.0)	6 (15.8)
No change	3 (5.0)	5 (6.1)	1 (2.0)	1 (2.6)
Slightly worse	3 (5.0)	4 (4.9)	2 (4.0)	4 (10.5)
Much worse	2 (3.3)	2 (2.4)	1 (2.0)	2 (5.3)
Missing		5 (6.1)	1 (2.0)	2 (5.3)
How are the problems related to your shoulder now compared with a year ago?				
Much better	43 (69.4)	61 (73.5)	34 (72.3)	30 (78.9)
Slightly better	10 (16.1)	16 (19.3)	9 (19.1)	4 (10.5)
No change	1 (1.6)			2 (5.3)
Slightly worse	3 (4.8)	1 (1.2)	1 (2.1)	
Much worse	2 (3.2)	5 (6.0)		1 (2.6)
Missing	3 (4.8)		3 (6.4)	1 (2.6)
How are the problems related to your shoulder now compared with 2 years ago?				
Much better	48 (82.8)	58 (71.6)	39 (86.7)	25 (69.4)
Slightly better	5 (8.6)	16 (19.8)	2 (4.4)	5 (13.9)
No change	1 (1.7)	1 (1.2)	1 (2.2)	2 (5.6)
Slightly worse	2 (3.4)	2 (2.5)	1 (2.2)	2 (5.6)
Much worse	1 (1.7)	2 (2.5)		
Missing	1 (1.7)	2 (2.5)	2 (4.4)	2 (5.6)
How pleased are you with your shoulder symptoms at 8 months?				
Very pleased	29 (48.3)	37 (45.1)	28 (56.0)	21 (55.3)
Fairly pleased	24 (40.0)	32 (39.0)	17 (34.0)	12 (31.6)
Not very pleased	6 (10.0)	5 (6.1)	2 (4.0)	2 (5.3)
Very disappointed	1 (1.7)	3 (3.7)	2 (4.0)	1 (2.6)
Missing		5 (6.1)	1 (2.0)	2 (5.3)
How pleased are you with your shoulder symptoms at 12 months?				
Very pleased	33 (53.2)	42 (50.6)	26 (55.3)	26 (68.4)
Fairly pleased	18 (29.0)	33 (39.8)	18 (38.3)	9 (23.7)
Not very pleased	6 (9.7)	3 (3.6)	1 (2.1)	
Very disappointed	2 (3.2)	5 (6.0)		2 (5.3)
Missing	3 (4.8)		2 (4.3)	1 (2.6)

continued

TABLE 53 Symptoms at 8, 12 and 24 months (*continued*)

Question	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
How pleased are you with your shoulder symptoms at 24 months?				
Very pleased	44 (75.9)	46 (56.8)	27 (60.0)	25 (69.4)
Fairly pleased	9 (15.5)	23 (28.4)	13 (28.9)	6 (16.7)
Not very pleased	1 (1.7)	6 (7.4)	3 (6.7)	1 (2.8)
Very disappointed	3 (5.2)	3 (3.7)		2 (5.6)
Missing	1 (1.7)	3 (3.7)	2 (4.4)	2 (5.6)

TABLE 54 Employment status at 8, 12 and 24 months

Employment status	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
Employed at 8 months				
Yes	27 (45.0)	38 (46.3)	21 (42.0)	20 (52.6)
No	33 (55.0)	37 (45.1)	28 (56.0)	16 (42.1)
Missing		7 (8.5)	1 (2.0)	2 (5.3)
Employed at 12 months				
Yes	29 (46.8)	34 (41.0)	16 (34.0)	20 (52.6)
No	31 (50.0)	48 (57.8)	29 (61.7)	17 (44.7)
Missing	2 (3.2)	1 (1.2)	2 (4.3)	1 (2.6)
Employed at 24 months				
Yes	25 (43.1)	30 (37.0)	16 (35.6)	19 (52.8)
No	32 (55.2)	48 (59.3)	27 (60.0)	15 (41.7)
Missing	1 (1.7)	3 (3.7)	2 (4.4)	2 (5.6)
If you are employed, are you off sick or working reduced duties because of your shoulder at 8 months?				
Yes, off sick	7 (11.7)	6 (7.3)	4 (8.0)	1 (2.6)
Yes, working reduced hours	1 (1.7)	6 (7.3)	3 (6.0)	4 (10.5)
No, working usual hours/duties	18 (30.0)	24 (29.3)	14 (28.0)	14 (36.8)
Missing	34 (56.7)	46 (56.1)	29 (58.0)	19 (50.0)
Are you currently out of work, off sick or working reduced duties because of your shoulder at 12 months?				
Yes	6 (9.7)	8 (9.6)	3 (6.4)	3 (7.9)
No	44 (71.0)	64 (77.1)	37 (78.7)	29 (76.3)
Missing	12 (19.4)	11 (13.3)	7 (14.9)	6 (15.8)
Are you currently out of work, off sick or working reduced duties because of your shoulder at 24 months?				
Yes, off sick	4 (6.9)	4 (4.9)	2 (4.4)	2 (5.6)
No, working usual hours/duties	48 (82.8)	64 (79.0)	38 (84.4)	28 (77.8)
Missing	6 (10.3)	13 (16.0)	5 (11.1)	6 (16.7)

TABLE 55 Health status at 8, 12 and 24 months

Measure	Stratum A, *n*, mean (SD)		Stratum B, *n*, mean (SD)	Stratum C, *n*, mean (SD)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
OSS				
Baseline	63, 25.6 (8.4)	85, 24.6 (7.8)	50, 25.5 (8.5)	40, 24.8 (7.7)
8 months	60, 35.9 (10.3)	81, 37.1 (8.4)	50, 37.6 (8.3)	38, 35.5 (10.6)
12 months	61, 38.6 (9.9)	82, 40.3 (8.2)	46, 40.0 (5.9)	38, 41.1 (6.9)
24 months (primary outcome)	57, 42.9 (7.1)	79, 42.0 (7.5)	45, 41.9 (5.9)	36, 42.7 (5.9)
SPADI				
Baseline	63, 63.7 (22.7)	85, 62.8 (21.6)	50, 61.5 (22.9)	40, 64.6 (17.7)
8 months	59, 30.4 (28.2)	80, 30.1 (27.4)	49, 28.6 (23.2)	36, 31.7 (26.1)
12 months	93, 23.1 (26.1)	83, 22.4 (25.5)	65, 21.5 (22.8)	37, 18.8 (21.6)
24 months	91, 15.2 (21.3)	81, 16.9 (22.7)	61, 13.8 (17.5)	34, 15.0 (22.2)
SPADI pain				
Baseline	63, 71.2 (19.9)	85, 71.7 (19.6)	50, 72.1 (21.4)	40, 74.6 (17.1)
8 months	60, 34.0 (27.9)	81, 32.8 (27.6)	50, 31.4 (24.8)	36, 35.9 (27.7)
12 months	61, 24.3 (26.8)	82, 24.4 (26.4)	46, 21.6 (17.3)	37, 21.9 (24.6)
24 months	57, 13.4 (18.0)	81, 18.7 (24.4)	42, 15.6 (15.3)	34, 16.9 (23.4)
SPADI disability				
Baseline	63, 59.0 (25.8)	84, 57.4 (24.8)	50, 54.9 (26.2)	40, 58.4 (20.1)
8 months	59, 28.2 (29.0)	80, 28.2 (27.9)	49, 26.5 (23.1)	37, 31.0 (28.3)
12 months	61, 21.0 (26.7)	83, 21.0 (26.0)	46, 16.9 (17.8)	37, 16.7 (20.3)
24 months	58, 11.5 (20.7)	81, 15.7 (22.4)	43, 14.1 (19.0)	34, 13.7 (22.2)
MHI-5				
Baseline	63, 21.9 (5.0)	85, 22.8 (4.5)	49, 22.9 (5.1)	40, 22.3 (4.7)
8 months	60, 23.5 (4.9)	81, 23.9 (4.4)	48, 24.1 (4.5)	38, 24.1 (4.1)
12 months	60, 23.3 (5.0)	82, 23.3 (4.9)	45, 25.0 (4.3)	37, 24.4 (3.9)
24 months	58, 24.7 (3.7)	81, 24.6 (4.6)	43, 23.9 (5.0)	34, 24.1 (4.9)
EQ-5D				
Baseline	62, 0.529 (0.315)	84, 0.509 (0.285)	50, 0.505 (0.320)	39, 0.472 (0.306)
8 months	59, 0.669 (0.332)	80, 0.713 (0.258)	45, 0.717 (0.233)	37, 0.668 (0.236)
12 months	61, 0.712 (0.308)	81, 0.715 (0.288)	45, 0.767 (0.212)	35, 0.748 (0.181)
24 months	57, 0.773 (0.236)	81, 0.782 (0.218)	45, 0.771 (0.223)	36, 0.788 (0.222)

TABLE 56 Magnetic resonance imaging results

Measure	Stratum A, *n* (%)		Stratum B, *n* (%)	Stratum C, *n* (%)
	Arthroscopic (*n* = 63)	Open (*n* = 85)	Arthroscopic (*n* = 50)	Open (*n* = 40)
MRI scans received	60	79	39	36
Result of MRI scan				
Re-tear	29 (48.3)	30 (38.0)	14 (35.9)	13 (36.1)
No tear	28 (46.7)	46 (58.2)	22 (56.4)	21 (58.3)
Inconclusive	1 (1.7)	1 (1.3)		
Missing	2 (3.3)	2 (2.5)	3 (7.7)	2 (5.6)
Size of tear if MRI scan shows a re-tear				
Partial	2 (6.9)	1 (3.3)	1 (7.1)	
Small	8 (27.6)	9 (30.0)	1 (7.1)	3 (23.1)
Medium	5 (17.2)	8 (26.7)	6 (42.9)	5 (38.5)
Large	5 (17.2)	3 (10.0)	2 (14.3)	2 (15.4)
Massive	7 (24.1)	7 (23.3)	3 (21.4)	3 (23.1)
Missing	2 (6.9)	2 (6.7)	1 (7.1)	

Appendix 2 Health economics complete case analysis

TABLE 57 Resource use relating to initial surgery: complete case analysis using the original data set, ITT analysis

	Stratum A				Stratum B	Stratum C
Outcome	Arthroscopic ($n = 136$), mean (SE)	Open ($n = 137$), mean (SE)	Arthroscopic vs. open mean difference (95% CI; p-value) (no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI; p-value) (adjusting for age, size of tear, centre)	Arthroscopic ($n = 91$), mean (SE)	Open ($n = 82$), mean (SE)
Theatre time (minutes)	($n = 109$), 67.2 (5.6)	($n = 119$), 70.7 (4.0)	($n = 228$) –3.5 (–16.8 to 9.9; 0.608)	($n = 163$) 12.1 (3.3 to 20.9; 0.007)	($n = 63$), 65.1 (5.8)	($n = 61$), 69.0 (6.9)
Anchor quantity	($n = 109$), 1.3 (0.1)	($n = 110$), 1.4 (0.1)	($n = 219$) –0.1 (–0.5 to 0.2; 0.553)	($n = 156$) 0.1 (–0.3 to 0.4; 0.647)	($n = 70$), 1.4 (0.1)	($n = 58$), 1.6 (0.2)
Nights in hospital	($n = 119$), 0.5 (0.1)	($n = 129$), 0.7 (0.1)	($n = 248$) –0.2 (–0.4 to 0.1; 0.281)	($n = 180$) –0.1 (–0.5 to 0.3; 0.589)	($n = 73$), 0.3 (0.1)	($n = 72$), 1.0 (0.1)

TABLE 58 Cost outcomes: complete case analysis using the original data set, ITT analysis

Outcome	Stratum A (£)				Stratum B (£)	Stratum C (£)
	Arthroscopic ($n = 136$), mean (SE)	Open ($n = 137$), mean (SE)	Arthroscopic vs. open mean difference (95% CI; *p*-value) (no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI; *p*-value) (adjusting for age, size of tear, centre)	Arthroscopic ($n = 91$), mean (SE)	Open ($n = 82$), mean (SE)
Theatre time	($n = 109$), 1104 (92)	($n = 119$), 1161 (65)	($n = 228$) –57 (–277 to 162; 0.608)	($n = 228$) 113 (–19 to 245; 0.093)	($n = 63$), 1070 (96)	($n = 61$), 1133 (114)
Anchor costs	($n = 109$), 134 (13)	($n = 110$), 147 (13)	($n = 219$) –13 (–50 to 24; 0.493)	($n = 219$) 1 (–25 to 27; 0.939)	($n = 70$), 148 (16)	($n = 58$), 170 (21)
Equipment costs	($n = 136$), 202 (12)	($n = 137$), 145 (7)	($n = 273$) 58 (31 to 84; 0.000)	($n = 273$) 77 (56 to 98; 0.000)	($n = 91$), 237 (13)	($n = 82$), 164 (9)
Total cost of surgery	($n = 91$), 1395 (134)	($n = 100$), 1381 (90)	($n = 191$) 14 (–299 to 327; 0.930)	($n = 191$) 250 (112 to 387; 0.000)	($n = 52$), 1422 (143)	($n = 47$), 1445 (167)
Nights in hospital	($n = 119$), 191 (40)	($n = 129$), 250 (37)	($n = 248$) –59 (–166 to 48; 0.281)	($n = 248$) –37 (–142 to 68; 0.485)	($n = 73$), 109 (22)	($n = 72$), 368 (51)
Total procedure-related costs	($n = 85$), 1522 (160)	($n = 94$), 1606 (114)	($n = 179$) –83 (–465 to 298; 0.666)	($n = 179$) 225 (56 to 395; 0.010)	($n = 46$), 1487 (168)	($n = 43$), 1674 (208)
Cost after surgery to 12-month follow-up	($n = 72$), 771 (75)	($n = 95$), 971 (107)	($n = 167$) –200 (–46 to 75; 0.153)	($n = 167$) –155 (–431 to 122; 0.271)	($n = 46$), 494 (70)	($n = 45$), 764 (118)
Total costs up to 12 months	($n = 45$), 2852 (249)	($n = 64$), 2915 (193)	($n = 109$) –63 (–680 to 554; 0.840)	($n = 109$) 231 (–216 to 679; 0.307)	($n = 24$), 2182 (293)	($n = 23$), 2526 (410)
Total cost from 12 to 24 months	($n = 115$), 175 (66)	($n = 117$), 116 (34)	($n = 232$) 59 (–87 to 205; 0.429)	($n = 232$) 61 (–87 to 209; 0.418)	($n = 76$), 119 (33)	($n = 70$), 95 (28)
Total cost over 24 months	($n = 40$), 2975 (264)	($n = 61$), 3080 (209)	($n = 101$) –105 (–770 to 561; 0.756)	($n = 101$) 10 (–502 to 523; 0.968)	($n = 22$), 2368 (298)	($n = 21$), 2714 (462)
Total cost over 24 months (discounted)	($n = 40$), 2974 (264)	($n = 61$), 3076 (208)	($n = 101$) –102 (–766 to 562; 0.760)	($n = 101$) 13 (–498 to 524; 0.959)	($n = 22$), 2362 (297)	($n = 21$), 2710 (461)

TABLE 59 Quality-of-life outcomes: complete case analysis using the original data set, ITT analysis

Outcome	Stratum A					Stratum B	Stratum C
	Arthroscopic ($n = 136$), mean (SD)	Open ($n = 137$), mean (SD)	Arthroscopic vs. open mean difference (95% CI; *p*-value) (no covariate adjustment)	Arthroscopic vs. open mean difference (95% CI; *p*-value) (adjusting for baseline EQ-5D, index)	Arthroscopic vs. open mean difference (95% CI; *p*-value) (adjusting for baseline EQ-5D, index, age, tear size, centre)	Arthroscopic ($n = 91$), mean (SD)	Open ($n = 82$), mean (SD)
QALYs from baseline to 8 months	($n = 120$), 0.41 (0.02)	($n = 123$), 0.40 (0.01)	($n = 243$) 0.00 (–0.04 to 0.04; 0.884)	($n = 243$) –0.01 (–0.03 to 0.01; 0.211)	($n = 243$) –0.01 (–0.04 to 0.01; 0.188)	($n = 79$), 0.41 (0.02)	($n = 74$), 0.41 (0.02)
QALYs from 8 months to 12 months	($n = 112$), 0.23 (0.01)	($n = 113$), 0.24 (0.01)	($n = 225$) –0.01 (–0.03 to 0.02; 0.671)	($n = 224$) –0.01 (–0.03 to 0.01; 0.328)	($n = 224$) –0.01 (–0.03 to 0.01; 0.444)	($n = 70$), 0.24 (0.01)	($n = 68$), 0.24 (0.01)
QALYs from 12 months to 24 months	($n = 111$), 0.74 (0.02)	($n = 111$), 0.74 (0.02)	($n = 222$) 0.00 (–0.06 to 0.07, 0.948)	($n = 221$) –0.01 (–0.07 to 0.05; 0.754)	($n = 221$) –0.01 (–0.07 to 0.06; 0.864)	($n = 74$), 0.73 (0.03)	($n = 69$), 0.75 (0.03)
Total QALYs over 24 months	($n = 106$), 1.41 (0.04)	($n = 106$), 1.40 (0.04)	($n = 212$) 0.01 (–0.11 to 0.13; 0.867)	($n = 212$) –0.02 (–0.12 to 0.07; 0.631)	($n = 212$) –0.01 (–0.11 to 0.10; 0.896)	($n = 66$), 1.43 (0.05)	($n = 64$), 0.42 (0.05)
Total QALYs over 24 months (time discounted)	($n = 106$), 1.38 (0.04)	($n = 106$), 1.37 (0.04)	($n = 212$) 0.01 (–0.11 to 0.13; 0.865)	($n = 212$) –0.02 (–0.12 to 0.07; 0.630)	($n = 212$) –0.01 (–0.11 to 0.09; 0.894)	($n = 66$), 1.40 (0.05)	($n = 64$), 1.39 (0.04)

Appendix 3 Trial protocol

Protocol for the UKUFF study: a pragmatic multi-centre randomised controlled trial of arthroscopic versus open surgical repair for degenerative rotator cuff tears.

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International Standard Randomised Controlled Trial Number (ISRCTN) ISRCTN97804283

HTA Project Number 05/47/02

ABSTRACT

This protocol describes a pragmatic multi-centre randomised controlled trial (RCT) to assess the clinical and cost-effectiveness of arthroscopic surgery and open surgery in the management of rotator cuff tears. This trial began in 2007 and was modified in 2010 with the removal of a non-operative arm due to high rates of early cross-over to surgery.

KEYWORDS

Shoulder, Rotator cuff, tendon, tears, surgery, arthroscopy

BACKGROUND AND RATIONALE

In 2000, an assessment of the prevalence and incidence of consultations for shoulder problems in UK primary care estimated the annual prevalence to be 2.4%, with the rate increasing linearly with age [1]. It is estimated that disorders of the rotator cuff account for between 30 and 70% of the shoulder pain cases that are reported [2, 3]. The clinical evidence available, regarding both the natural history and management of rotator cuff tears, is limited and conflicting, most reports are small scale, (<50 cases), single centre, retrospective cohort studies [4-11].

Rotator cuff tears can be treated both surgically (arthroscopic and open) and non-surgically (for example by injection and exercises). Traumatic tears are uncommon: most patients present through age related degeneration of tendon attachment to bone at the proximal humerus. Surgical repair may be considered for patients with persistent symptoms who fail to respond to rest and conservative care. Such non-operative care will usually include physiotherapy and glucocorticoid injections into the shoulder.

A rotator cuff repair operation aims to re-attach the tendons to the bone. The repair may also include an acromioplasty where overhanging bone and soft tissue above the tendon are excised with the aim of creating more space for the rotator cuff tendons to move freely.

In general, two approaches are available for surgical repair.

- Open/mini-open surgery involves the rotator cuff being repaired under direct vision through an incision in the skin.

- Arthroscopic surgery involves the repair being performed through arthroscopic portals.

Proponents of arthroscopic rotator cuff surgery suggest that the procedure may have advantages over standard open techniques by causing less trauma to the deltoid muscle and overlying soft tissue. Arguably this causes less post-operative patient discomfort together with earlier return of movement. However, the success of the repair depends on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open/mini-open surgery. Other potential disadvantages of the arthroscopic approach include increased technical difficulty and longer time in theatre. Only a few, small, non-randomised controlled trials have directly compared procedures and, therefore, there is a need to compare the outcome of the two surgical techniques [12].

The primary objective of this study is to conduct a pragmatic multicentre randomised clinical trial to obtain good quality evidence of the effectiveness and cost-effectiveness of arthroscopic versus open surgical repair for the treatment of degenerative rotator cuff tears.

METHODS

Design

At the outset of the UKUFF trial in 2007 a 3 way parallel group randomised trial began comparing arthroscopic rotator cuff repair surgery with open or mini-open rotator cuff repair surgery with a rest then exercise programme of non-operative care [UKUFF Original REC Version Number Version 07/Q1606/49]. Figure 1 presents the original version as a flowchart.

The trial was adapted and reconfigured by the funder in 2009, (after consultation with the trial steering and data monitoring committees), into a 2 way parallel group RCT, due to a high rate of cross-over of patients (77%) from the rest then exercise programme to surgery (UKUFF Reconfigured REC Reference Number 10/H0402/24). 87 patients were carried through to the subsequent reconfigured trial. After the reconfiguration, it was calculated a further 180 patients be recruited and followed-up for two years as per the original protocol. (providing a total of 267 patients treated with surgery). It is the reconfigured design that is presented in this protocol.

UKUFF (reconfigured) is a pragmatic multi-centre study involving 20 surgeons from 16 UK centres. It includes patients over 50 years of age, with a diagnosis of a full thickness rotator cuff tear who are deemed eligible for surgery. Patients are randomised to either open or arthroscopic repair while the surgeons perform their usual and preferred surgical technique using one of these approaches. Patients are followed up with telephone and postal questionnaires for 24 months, and an MRI (Magnetic Resonance Scan) or USS (Ultrasound Scan) 12 months after their surgery. The primary outcome is the Oxford Shoulder Score at 24 months [13]. The study is led by clinicians (both surgeons and physiotherapists), methodologists, statisticians and health economists.

Surgeon eligibility

Participating surgeons require a 'minimum level of expertise' for the types of surgery undertaken. For both surgical techniques only consultant orthopaedic shoulder surgeons with a minimum of two years experience in consultant practice can participate. For those surgeons performing both arthroscopic surgery and open surgery, only those who have performed a minimum of 5 cases per year are considered eligible. The participating surgeons represent a cross-section of high, medium and low volume practitioners undertaking both arthroscopic and open surgery.

Recruitment and treatment allocation

Support from local research networks is used, where possible, to help with patient identification, recruitment and with obtaining any required data from patient notes. The eligibility of the patient is confirmed by the local consultant orthopaedic surgeon.

Patient eligibility

The patient is eligible for the study if they are:

- Aged at least 50 years
- Suffer from a degenerative rotator cuff tear
- Have a full thickness rotator cuff tear
- Rotator cuff tear diagnosed using MRI or Ultrasound scan
- Able to consent

The patient is excluded if ANY of the following apply:

- Previous surgery on affected shoulder

- Dual shoulder pathology
- Traumatic Tear
- Significant problems in the other shoulder
- Rheumatoid arthritis/Systemic disease
- Significant osteoarthritis problems
- Significant neck problems
- Cognitive impairment or language issues
- Unable to undergo an MRI scan for any reason

There is no formal age limit. However, patients aged 85 years and over are not expected to be eligible to participate. Consent is obtained either locally, by a research nurse, or remotely by the study office in Oxford. Only when the consent form and the baseline questionnaire have been returned is the participant entered into the trial and randomised to one of the surgical options. Randomisation is by computer allocation at the Health Services Research Unit, University of Aberdeen. Allocation was minimised using surgeon, age and size of tear. After randomisation the participant is considered irrevocably part of the trial for the purpose of the research, irrespective of what occurs subsequently.

Patients are free to withdraw at any time without consequence to the health care they receive.

Randomised Surgery

Details of the surgical technique used (including method of repair and theatre equipment used e.g. types of suture) are recorded on a standard form, as well as the size of the tear, the appearance of the tendons involved, the ease of repair and the completeness of the repair. If circumstances dictate that the allocated surgical technique cannot be carried out then any alternative procedure is recorded. The surgeon contacts the study office if their patient is unwilling or unable to have the operation on the arranged date. Patient progress through the study is detailed in Figure 2. UKUFF Flow Chart.

DATA COLLECTION AND PROCESSING

Outcome assessments involve patient completed questionnaires and 12 month post-surgery imaging.

Questionnaires

A combination of the Oxford Shoulder Score (OSS) [13], the Shoulder Pain and Disability

Index (SPADI) [14], the Mental Health Inventory (MHI-5) [15] and the EQ-5D [16] is used to assess functional outcome and patient-reported quality of life. These assess a range of symptoms often experienced with rotator cuff tears e.g. pain, weakness and a loss of function. Outcome assessments are conducted by participant self-completion questionnaires and as such, interviewer bias and clinical rater bias are avoided. This form of outcome measurement has consistently performed well in comparison to clinician based assessments and general health status measures. All participants, including those who withdraw from their allocated intervention but who still wish to be involved in the study, are followed up, with analysis based on the intention to treat principle.

Participants will receive questionnaires at the following time points:

- Baseline questionnaire – completed before randomisation
- 2 and 8 weeks post treatment – questionnaire completed over the phone
- 8, 12 and 24 months post randomisation

The baseline, 12 and 24 month post randomisation questionnaires also collect information to inform a cost-effectiveness element. Questions relating to information on primary care consultations, other consultations, out-of-pocket costs and work-impact of the intervention received are included. The study office in Aberdeen will contact and follow-up participants whose questionnaires have not been returned.

4.2 Post-operative Imaging

A number of authors have reported high rates of re-rupture of the rotator cuff tear (20-54%) after surgery, with some reporting a significant correlation between re-rupture and poor outcome [17]. Rates of re-rupture or repair failure may differ between the two surgical techniques. For this reason, participants will undergo an MRI or USS at 12 months post operation to assess the state of the rotator cuff repair. These are arranged by the study office in Oxford and performed locally. The images are collected centrally and read by an independent consultant radiologist blind to the type of surgery performed. The results of the scan are not reported to the participating surgeons. Incidental abnormalities of clinical significance are reported to the surgeon.

5. ANALYSIS

Statistical analyses are based on all people randomised, irrespective of subsequent compliance with the randomised intervention. The principal comparisons will be all those allocated arthroscopic surgery versus all those allocated open surgery. The analyst will be blinded to the allocation.

Measure of outcome

Primary outcome measure:

- Oxford Shoulder Score at 24 months after randomisation

Primary measure of cost-effectiveness:

- Incremental cost per quality-adjusted life year gained

Secondary outcome measures include:

- Oxford Shoulder Score (OSS) at 12 months after randomisation
- EQ-5D at 8, 12, 24 months after randomisation
- MHI-5 at 8, 12, 24 months after randomisation
- Shoulder pain and disability index (SPADI) at 8, 12, 24 months after randomisation
- Participant's rating of how pleased they are with shoulder symptoms at 12, 24 months after randomisation
- Participant's view of state of shoulder at 8, 12, 24 months after randomisation
- Surgical complications (intra and post-operative) at 2 and 8 weeks post surgery and at 12 and 24 months after randomisation
- Net health care costs at 2 weeks, 12 and 24 months after randomisation; out of pocket costs and work impact.

Planned subgroup analyses

(i) Size of tear (small versus medium/large);

(ii) Age < or equal to 65 or >65;

Stricter levels of statistical significance ($p<0.01$) will be used in subgroup analyses reflecting their exploratory nature and the multiple testing involved.

Statistical analysis

Reflecting the possible clustering in the data, the outcomes will be compared using multilevel

models, with adjustment for minimisation variables and participant baseline values. Statistical significance is set at the 2.5% level with corresponding confidence intervals. All participants will remain in their allocated group for analysis (intention to treat). Per-protocol analysis will also be performed.

Economic evaluation

A cost-effectiveness analysis will be performed. A simple patient resource use questionnaire at baseline and at 12 and 24 months post randomisation is used to obtain information on primary care consultations, other consultations, out-of pocket costs, work-impact of the intervention received and return to work. Unit costs will come from national sources and participating hospitals. The patient questionnaire is also used to administer the EQ-5D. The main health economic outcome is within-trial and extrapolated quality adjusted life-years, estimated using the EQ-5D.

Incremental cost-effectiveness will be calculated as the net cost per quality-adjusted life year gained, for arthroscopic surgery versus open surgery. Power calculations (see following section) have been based on clinical rather than cost-effectiveness outcomes, which will be estimated rather than used in hypothesis testing. Cost-effectiveness ratios and net-benefit statistics will be calculated. We will report within-trial cost-effectiveness and explore if the trial produces sufficient evidence to plausibly model future quality of life or costs (e.g. based on projected failure rates). We will also extrapolate long-term cost-effectiveness beyond the trial period.

An important component of this trial will be assessment of cost. Therefore, an accurate record of procedures at each of the proposed centres is essential. To evaluate costs of each type of surgery, information from the operating theatres will be collected. Theatre managers will be contacted and visited at each site. Resources used, equipment costs and standard procedures for rotator cuff repairs will be recorded. Per case information will also be analysed during the final analysis. A checklist of equipment, consumables, implants, time and staff utilized during each case will be completed by theatre staff. Information from theatres will be collected by the Oxford UKUFF office and will be used in a cost comparison between the arthroscopic and open surgery.

SAMPLE SIZE AND FEASIBILITY

Sample size sought

The sample size was designed to detect a difference in OSS score of 0.38 of a SD for the comparison of arthroscopic versus open surgery. This was based on our experience of using and developing the OSS score in a variety of settings, from which a 3 point difference (0.33 of a SD) would be deemed a clinically important change. Attrition is expected to be low (10%), as are the effects of clustering of outcomes [18, 19] (intra cluster correlation (ICC) less than 0.03). Whilst we did not have a direct estimate from a shoulder trial, other orthopaedic datasets available to our team supported this low ICC estimate. Both these factors required the sample size to be inflated; however, the primary analysis will be adjusted for baseline OSS score which conversely allowed the sample size to be decreased by a factor of 1-correlation squared [20]. Our previous studies showed that the correlation in the OSS score pre surgery to 6 months post surgery in patients similar to potential trial participants was 0.57. Assuming a conservative correlation of 0.5 implied that the sample size could be reduced by 25% and still maintains the same power. Therefore, a study with a total of 267 participants was considered sufficiently powered to detect a clinically important change in each comparison, assuming attrition and clustering accounted for approximately 25% of variation in the data.

ORGANISATION

Trial Timeline

The trial began in December 2007 and was stopped in December 2009 to allow for reconfiguration. Funding approval of the reconfiguration was given in January 2010 and revised research ethics approval was granted in April 2010. In May 2010 recruitment started to the reconfigured design. The final follow-up assessment is planned for December 2013. Analysis and write up are planned for January to July 2014, with publication and dissemination from August 2014 onwards.

Central organisation of the study

Oxford coordinates the site specific and clinical concerns while Aberdeen houses the database and randomisation systems. The study is overseen by an independent Trial Steering Committee and an independent Data Monitoring Committee.

Protocol Amendments

Small changes have been made to the protocol over time, to reflect changes in points of outcome data collection and recruitment procedures. Some changes have been made in response to alterations in waiting times for surgery in the NHS that occurred during the trial period. Support for individual centres also changed after the inception of the NIHR in the UK and the provision of a regional network of research support through the UK Comprehensive Research Network (UKCRN).

PUBLICATION

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR HTA programme. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. The main report will be drafted by the UKUFF Management Group, and the final version will be agreed by the Trial Steering Committee before submission for publication, on behalf of the UKUFF collaborators.

Trial Status

UKUFF completed recruitment in February 2012 and follow up will be completed by January 2014. Production of the monograph is planned for July of 2014.

Competing Interests

The authors declare that they have no competing interests.

Author's contributions

All of the authors contributed to the design and development of the study protocol. CC and AJC were responsible for writing this manuscript. All authors read, commented on and approved the final manuscript.

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(HTA).

The trial sponsor is the University of Oxford.

Feedback on trial design and implementation and support for the trial have been obtained over a protracted period from a large number of people. These include:

- Past trial coordinators: Dr Suzanne Breeman, Dr Julie Murdoch, Dr Joy Eldridge, Miss Loretta Davies
- Trial Steering Committee: Professor Jane Blazeby (Chair), Mr David Stanley, Dr Andrew Cook, Ms Jo Gibson and Major General Dair Farrar Hockley, Professor Jeremy Fairbank
- Data Monitoring Committee: Professor Roger Emery (Chair), Professor Jeremy Lewis and Dr Richard Morris

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FIGURE 1. ORIGINAL FLOWCHART

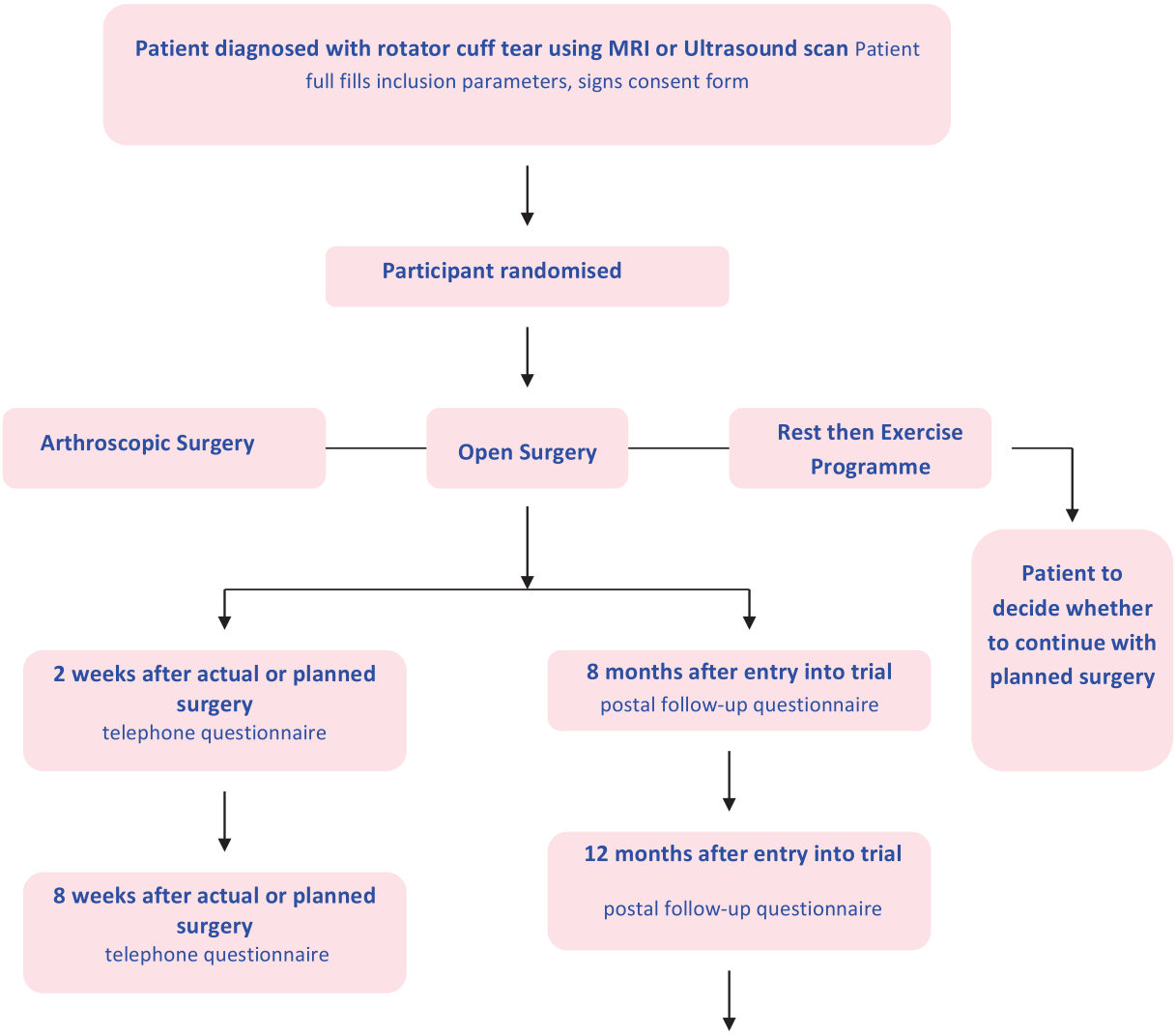
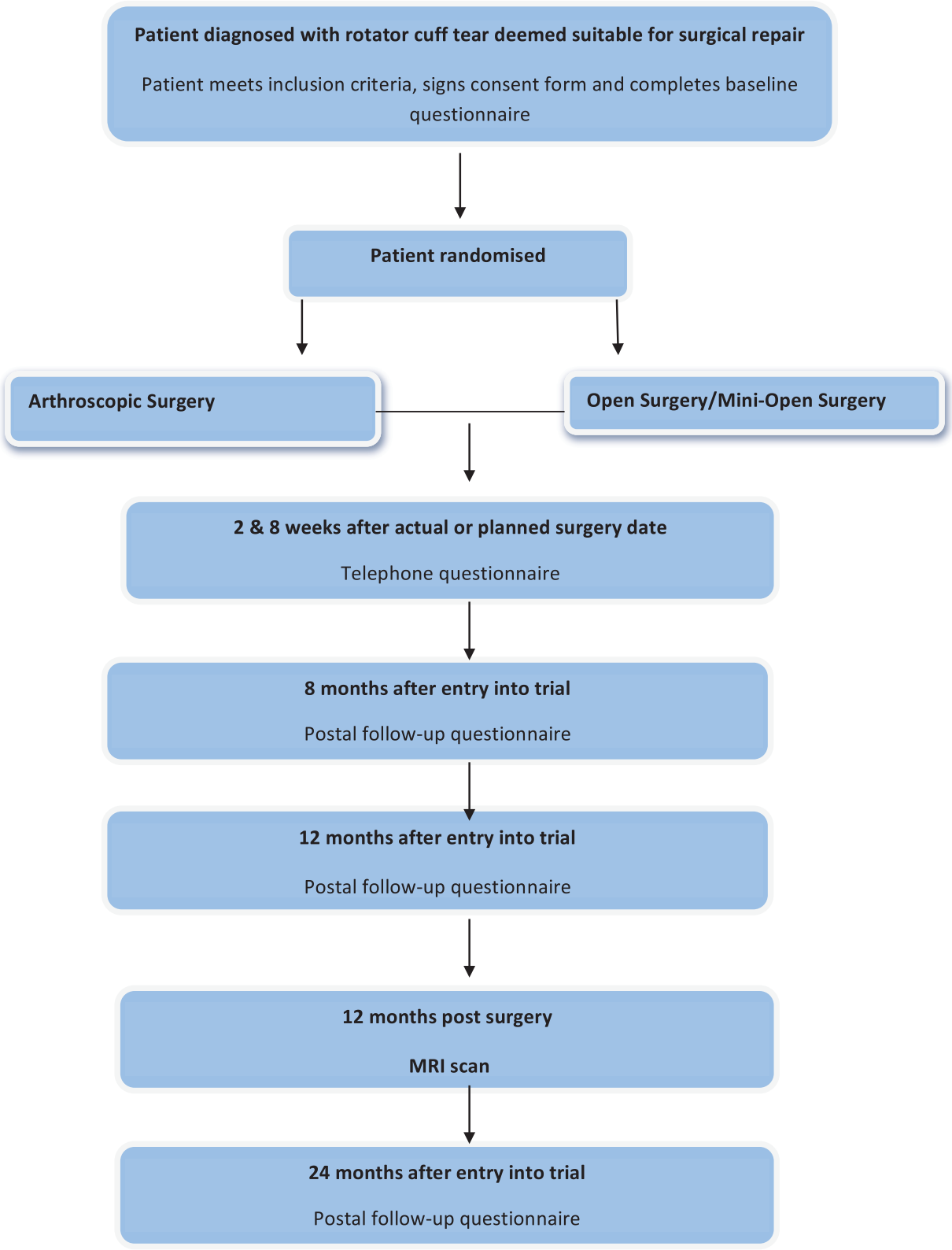


FIGURE 2. RECONFIGURED FLOW CHART



Appendix 4 Search terms used in the literature review

MEDLINE (OVID platform): 1946 to March Week 4 2014

Using the Cochrane sensitivity- and precision-maximising version RCT filter (2008 version).

1. exp Shoulder/
2. shoulder$.tw.
3. exp Shoulder Joint/
4. exp Shoulder Pain/
5. exp Rotator Cuff/
6. rotator cuff$.tw.
7. exp Acromion/
8. acromion$.tw.
9. exp Scapula/
10. musculotendinous cuff$.tw.
11. (degenerative adj tear$).ti,ab.
12. or/1-11
13. exp Joints/
14. exp Tendons/
15. exp Tendinopathy/
16. exp Bursitis/
17. exp Calcinosis/
18. exp Calcium/
19. exp Joint Diseases/
20. or/13-19
21. 12 and 20
22. exp Shoulder Impingement Syndrome/
23. subacromial impingement.tw.
24. ((shoulder$ or rotator cuff or scapula or subacromial or acromion) adj5 (joint$ or tendon$ or bursitis or calcinosis or calcium or impinge$)).tw.
25. or/21-24
26. exp General Surgery/
27. surg$.tw.
28. su.fs.
29. exp Decompression, Surgical/
30. decompress$.tw.
31. bursectom$.tw.
32. acromioplast$.tw.
33. (calcium adj remov$).tw.
34. exp Debridement/
35. debrid$.tw.
36. exp Arthroscopy/
37. arthroscop$.tw.
38. Orthopedics/
39. (open adj procedure$).ti,ab.
40. (open adj technique$).ti,ab.
41. mini-open.ti,ab.
42. or/26-41

43. 25 and 42
44. Randomised controlled trial.pt.
45. controlled clinical trial.pt.
46. Randomised.ab.
47. placebo.ab.
48. clinical trials as topic.sh.
49. randomly.ab.
50. trial.ti.
51. or/44-50
52. exp animals/ not humans.sh.
53. 51 not 52
54. 43 and 53
55. Limit 54 to yr="2006-2014"

Appendix 5 Operation record

UK Rotator Cuff Surgery Trial
UKCUFF

Patient Sticky

Consent form sited:

.....
UKUFF SURGEON

Study No ☐☐☐☐☐ **(if known)**

Date (day/month/year).....
Hospital.....
Operating Consultant.....

Procedure Side: **Left** ☐ **Right** ☐

TYPE OF SURGERY: **Open** ☐ **Mini-open** ☐ **Arthroscopic** ☐

Total time in theatre .....**minutes** **Operation time** ..... **minutes**
(including anaesthetic time)

STAFF IN THEATRE:
Assisting Surgeon: Consultant ☐ Fellow ☐ Registrar ☐ SHO ☐

Anaesthetist: Consultant ☐ Registrar ☐ SHO ☐

Number of Nursing/ODP Staff: .....

ANAESTHETIC:
GA ☐ Regional Block ☐ Combined ☐
LA top up ☐ Intra-articular infiltration ☐ Indwelling Catheter ☐

SURGICAL APPROACH:
Patient Position: Supine (Beach Chair) ☐ Lateral ☐

Surgical Approach: Deltoid Split ☐ Deltoid detached ☐

No of Portals (arthroscopic)_____

Ease of Repair: Easy ☐ Moderate ☐ Difficult ☐ Impossible ☐

Size of Tear: Small ____cm ☐ Medium_____cm ☐
Large ____cm ☐ Massive_____cm ☐
No Tear ☐

Surgical opinion of completeness of repair:
Poor ☐ Good ☐ Excellent ☐

If "No Tear" or "Impossible" No other procedure performed ☐
SAD only ☐
SAD & AC Joint Exc ☐
Other_____ ☐

OTHER:
Normal Saline Used 1L ☐ 2L ☐ 3L ☐ Other ☐ .....mls/litres
Fluid Management System Yes ☐ No ☐
Drains Yes ☐ No ☐

UKUFF Trial Co-ordinator Cushla Cooper [redacted]

CDR UKUFF OP NOTES 02/05/2008 VERSION 5

Consent form sited:

.....
UKUFF SURGEON

IMPLANTS:
Eg: Twinfix Anchor, Fibrewire

NAME:.....

QUANTITY:.....

Please insert product stickers if available

HOW HAVE YOU IMMOBILISED THE PATIENT'S SHOULDER?
Polysling ☐ Abductor Splint ☐ Other ☐

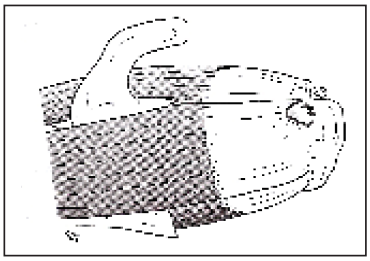
HOW LONG DO YOU PLAN TO IMMOBILISE THIS PATIENT FOR?
6 weeks ☐ 4 weeks ☐ 3 weeks ☐ 2 weeks ☐ Other ☐ _____

INTRA-OPERATIVE PROBLEMS
Anaesthetic problems (i.e.: respiratory, cardiac, anaphylaxis) ☐
Equipment problems (i.e.: VDU, FMS, camera, resector, instruments) ☐
Implant problems (i.e.; size unavailable, quantity unavailable) ☐
Surgical problems (i.e.; bleeding) ☐
Other (i.e.; staffing) ☐
Please describe:.....

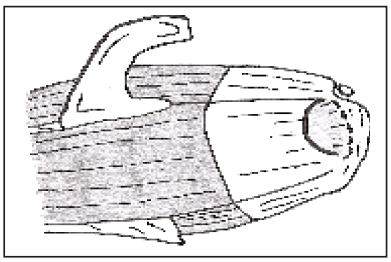
DID THIS CAUSE THE PLANNED PROCEDURE TO CHANGE **(ie; proceeded to open from arthroscopic)**
Yes ☐ **No** ☐ **Unsure** ☐

PLEASE MARK ORIGIN OF TISSUE SAMPLE ON THE PICTURE WHICH CORRESPONDS WITH THE SIZE OF THE TEAR (X)

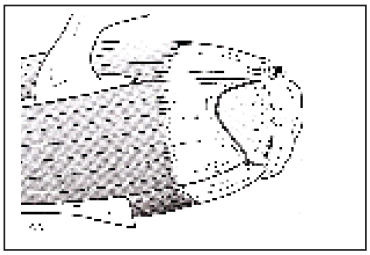
SMALL



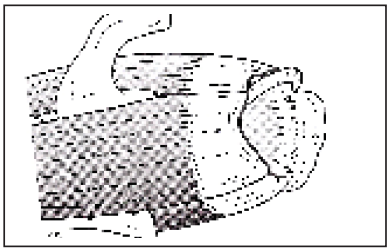
MEDIUM



LARGE



MASSIVE



UKUFF Trial Co-ordinator Cushla Cooper [redacted]

CDR UKUFF OP NOTES 02/05/2008 VERSION 5

Appendix 6 Patient information sheet

UK Rotator Cuff Surgery Trial
UKUFF

PATIENT INFORMATION SHEET

This study is about the clinical and cost effectiveness of surgical (arthroscopic or open) repairs for management of the rotator cuff tears. (10/H0402/24)

We are inviting you to take part in a research study. Before you decide whether to participate or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to decide whether or not you wish to be involved.

1. What is the purpose of this study?

The rotator cuff is a group of muscles that control movements within the shoulder. Tears of the rotator cuff are one of the most common causes of shoulder pain and dysfunction. Many patients require surgery to repair the tear, as non-surgical treatment like physiotherapy may not have helped restore shoulder function satisfactorily. Operations to repair the tendon can be done via an:

- Arthroscopic technique – where the tear is repaired through key-hole surgery, or a
- Mini-open/Open technique – where a longer skin incision is made to complete the repair procedure.

This study was designed to assess the best surgical technique for rotator cuff tears both in terms of recovery for patients and the costs involved.

2. Why have I been chosen?

You have been chosen because you are 50 years of age or older and have been diagnosed with a rotator cuff tear, deemed suitable for surgical repair.

3. Do I have to take part?

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason.

4. What will happen if I take part?

Sometimes we don't know which way of treating patients is best. To find out, we need to make comparisons between different treatments. To do this we will randomly allocate you to one of the following surgical options:

1. Arthroscopic Surgical Repair
2. Mini-open/Open Surgical Repair

Your surgeon routinely performs both these operations. Whichever one you are allocated to will be performed in the usual way by your surgeon. The benefits and problems associated with each treatment will be compared. This is called a randomised study.

5. What do I have to do?

If you agree to participate in the UKUFF trial, we may ask you for a blood sample. We hope to identify genes responsible for tears of the rotator cuff. We will provide you with the blood sample tubes and ask you take the equipment with you to your outpatients or pre-admission clinic appointment and ask to have the samples taken there. Due to the genetic nature of the blood analysis, only patients who identify as White British will be asked to give a blood sample.

You will also be asked to give a tissue sample. The tissue sample will be taken during your operation and is a very small amount which is routinely excised during rotator cuff repairs. The samples will be used to examine the condition of the tendon.

Involvement in the UKUFF trial will include completing questionnaires. These are specialised questionnaires, recognised as a means of assessing shoulder pain and function, and they also cover other health related questions. These will all be sent to you in the post with a free post envelope for them to be returned to our data centre. Follow up questionnaires will occur as follows:

- **At two and eight weeks** after the completion of the Rest then Exercise Programme/or two and eight weeks after your surgery, a member of the research team will ask you questions over the telephone.
- **8 months, 12 months and 24 months** after you first agreed to participate in the study a questionnaire will be sent to you in the post
- **12 months after your operation** you will be asked to undergo an MRI scan. The MRI scan is a detailed method of assessing the clinical and physical result of the operation.

.
A diagram illustrating your involvement in the study is attached at the end of this information sheet.

6. Expenses and payments
If you are asked to attend an MRI scan 12 months after your operation, the costs incurred during this extra appointment will be reimbursed on request.

7. What are the possible benefits of taking part?
Your rotator cuff tear will be treated by experienced surgeons using widely recognised treatments. The information we get from this study will help improve the future treatment of people with rotator cuff tears.

8. What are the possible risks of taking part?
MRI is a safe and non-invasive technique, which does not involve ionising radiation. An MRI safety questionnaire will be asked at the time of arranging the scan appointment to help identify and minimise any possible risks.

9. Will my taking part be kept confidential?
All patient information is stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with you will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

10. What if I change my mind about taking part?
If you decide to withdraw from the study, your standard of care will not be affected. You will **still** be asked to attend the usual follow-up clinics required by your surgeon and hospital. These will not be part of the study.

11. What if there is a problem?
Complaints If you wish to complain formally, you can do this through the NHS Complaints Procedure, (details can be obtained from your hospital) or you can find further information on ethics in research on the National Research Ethics Service website (www.nres.npsa.nhs.uk).

Harm If you are harmed and this is due to someone's negligence then you may have grounds for legal action or compensation against the University of Oxford (in respect of any harm arising out of the participation in the Clinical Trial) or the NHS (in respect of any harm which has resulted from the clinical procedure being undertaken).

12. Will my GP be informed of my involvement in the study?
With your consent your GP will be notified of your participation in the UKUFF study.

13. What will happen to any samples I give?
The tissue and blood samples collected for the UKUFF trial will be sent to the Nuffield Department of Orthopaedic Surgery, in Oxford, for analysis.

14. How will the information I provide be used?
We plan to publish the results in a health journal so others can read about and learn from the results of the study.

15. Who is organising and funding the research?
This nationwide trial is being funded through the Heath Technology Assessment (HTA) Programme, which is part of the Department of Health. You can access information about them on the HTA website (www.hta.nhs.uk).

The Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal Sciences (www.ndorms.ox.ac.uk) a department of the University of Oxford, in Oxford will undertake the day to day running of the trial, under the supervision of Professor Andrew Carr. The University of Oxford will act as a sponsor for the study and will be responsible for the governance of the trial.

The Centre for Healthcare and Randomised Trials (CHaRT), Health Services Research Unit in the University of Aberdeen (www.charttrials.abdn.ac.uk) in Aberdeen will be responsible for collecting and monitoring the information generated.

16. Who has reviewed this study?

A Research Ethics Committee, the UK Comprehensive Research Network, each hospital's Research and Development Committee/Department and your local Orthopaedic Consultant have reviewed this study.

17. Further Information

If you require more information about this study please call one of the telephone numbers provided to speak to a clinical member of the research team or, alternatively look at the study website www.charttrials.abdn.ac.uk/ukuff.

Thank you for reading this.
If you have any questions or would like any more information please contact the UKUFF Study Office by phone:
XXXXX
Or email XXXXX

Please keep this information sheet for your records.

If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you.

Appendix 7 Baseline questionnaire

Baseline Questionnaire

Study Number: | | | | | |

UK Rotator Cuff Surgery Trial

UKCFF

CONFIDENTIAL

UKUFF SHOULDER TRIAL

PATIENT ASSESSMENT

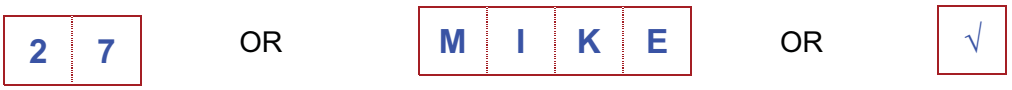
BASELINE QUESTIONNAIRE

Thank you for helping us with our research into rotator cuff tears.
We would be very grateful if you could complete and return this questionnaire in the enclosed freepost envelope.

ISRCTN No: 97804283
Version 1 01/02/07

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:



Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions, we would like you to think about different time periods, such during the last 4 weeks. Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

Thank you for your help.

Section 1 - Demographics

1. How old are you? ☐☐ years old

Please tick ONE box for EACH question

2. Gender: Are you … Male ☐ Female ☐

3. Education: Which of these best describes your highest qualification?

No formal qualifications	Secondary/further education *(eg: GCSE, 'O' Level, vocational qualification)*	Higher education *(eg: diploma, degree, postgraduate qualification)*
☐	☐	☐

4. Housing tenure: Which best applies to you?

Home owner *(including mortgage/loan)*	Private rent	Council rent	Other
☐	☐	☐	☐

5. Do you live on your own? Yes ☐ No ☐

6. What is your current employment status?

Employed full time *(including self-employed)*	Employed part time *(including self-employed)*	Homemaker/Car
☐	☐	☐
Retired	**Student**	**Unemployed**
☐	☐	☐

If you are employed:

6a. How would you describe your work?

Manual	Non-manual	Not sure
☐	☐	☐

6b. Are you currently 'off sick' or working reduced duties <u>because of your shoulder</u>?

Yes 'off-sick'	Yes working reduced hours/duties	No working usual hours/duties
☐	☐	☐

If you are <u>un</u>employed:

6c. Are you currently unable to work <u>because of your shoulder</u>?

☐ ☐

Everyone

7. Are you right or left-handed?

Right-handed ☐ Left-handed ☐ Both ☐

8. For how long (approximately) have you had this problem with your shoulder?

☐☐ Years ☐☐ Months

9. Would you be able to do your job OR essential everyday activities, if you had your 'bad' arm in a sling?

No ☐ Yes, but with difficulty ☐ Yes, with no difficulty ☐

Section 2 – Your Views About Surgery

- We would like to ask you about your personal views about **surgery in general**
- Below are 4 statements other people have made about **surgery in general**
- Please indicate the extent to which you agree or disagree with them by putting a tick (✓) in the appropriate box

There are no right or wrong answers. We are interested in your personal views.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
Doctors rely on surgery too much	☐	☐	☐	☐	☐
Doctors place too much trust in surgery	☐	☐	☐	☐	☐
I worry about the risks of surgery	☐	☐	☐	☐	☐
Surgery should only be taken as a last resort	☐	☐	☐	☐	☐

Section 3 – Shoulder Pain

Please tick ONE box for EACH question

During the past 4 weeks

1. How would you describe the worst pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
☐	☐	☐	☐	☐

During the past 4 weeks

2. Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

During the past 4 weeks

3. Have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

During the past 4 weeks

4. Have you been able to use a knife and fork - at the same time?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks …

Please tick ONE box for EACH question

During the past 4 weeks

5. Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

6. Could you carry a tray containing a plate of food across a room?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

7. Could you brush/comb your hair with the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

8. How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

During the past 4 weeks …

Please tick ONE box for EACH question

During the past 4 weeks

9. Could you hang your clothes up in a wardrobe, - using the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With great difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

10. Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

11. How much has pain from your shoulder interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

During the past 4 weeks

12. Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

Section 4 – Shoulder Pain and Disability

Please ring round ONE number to EVERY question where
0 = no pain and 10 = worst pain imaginable

PAIN SCALE DURING THE PAST WEEK

How severe is your shoulder pain .....

1. At its worst?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
2. When lying on involved side?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
3. Reaching for something on a high shelf?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
4. Touching the back of your neck?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
5. Pushing with the involved arm?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable

Please ring round ONE number to EVERY question where
0 = no difficulty and 10 = so difficult required help

DISABILITY SCALE DURING THE PAST WEEK

How much difficulty do you have.....

1. Washing your hair?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
2. Washing your back?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
3. Putting on an undershirt or pullover sweater?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
4. Putting on a shirt that buttons down the front?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help

Please ring round ONE number to EVERY question where 0 = no difficulty and 10 = so difficult required help

How much difficulty do you have.....

5. Putting on your pants?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
6. Placing an object on a high shelf?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
7. Carrying a heavy object (> 10 pounds)?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
8. Removing something from your back pocket?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help

Section 5 - Your General Health

State of Mind

Please tick ONE box for EACH question

1. How much time during the past month:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
b) Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
c) Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
d) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
e) Have you been a happy person?	☐	☐	☐	☐	☐	☐

Your Health Today

Please indicate which statement describes your own health state today.

Please tick ONE box for EACH question.

a) Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

b) Self-care

- I have no problems with self care ☐
- I have some problems with washing or dressing myself ☐
- I am unable to wash and dress myself ☐

c) Usual activities

- I have no problem in performing my usual activities (eg: work, study, housework, leisure activity) ☐
- I have some problems in performing my usual activities ☐
- I am unable to perform my usual activities ☐

d) Pain / Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

e) Anxiety / Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Section 6 – Health Service Use, and Costs

We would like to know how much contact you have had with the health service over the last 12 months. If you are not exactly sure, we would rather have your best guess than no information at all. Please answer every question, even if the answer is "0".

Please fill in both boxes, for example: 0 3 **if seen three times.**

Over the last 12 months, how many times have you:

1. **Seen your GP about your shoulder? ……** ☐☐
2. **Seen a practice nurse about your shoulder? …… ……** ☐☐
3. **Seen a physio or occupational therapist about your shoulder? ……** ☐☐
4. **Visited a hospital out-patient clinic about your shoulder? ……** ☐☐
5. **Been in hospital overnight because of your shoulder? ……** ☐☐

   5a. **If you have been in hospital overnight because of your shoulder, for how many nights were you there ? ……** ☐☐
6. **Visited a private practitioner such as an osteopath or chiropractor about your shoulder? ……** ☐☐

Over the last 12 months, approximately how much (to the nearest £) did the following items cost you? If there was no cost, please write "0".

7. **Buying painkillers, creams and lotions, dressings or slings as a result of your shoulder ……** £ _____
8. **Transport, parking, or other costs of visiting the GP or physio, attending exercise clinics, or other health service visits about your shoulder ……** £ _____
9. **Paying for private practitioners such as osteopaths or chiropractors about your shoulder ……** £ _____
10. **Losing earnings as a result of your shoulder ……** £ _____

Finally:

Date you filled in this questionnaire D D / M M / Y Y Y Y

THANK YOU

Thank you for completing this questionnaire. The information you have given us will be extremely useful.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Oxford in the envelope provided.

Please could you inform us of any changes to your phone number:

And inform us of any changes to your contact details: .....

.....

.....

Thank you again for your help.

If you would like any further information or have any queries about the study, please contact:

The UKUFF Study Office in Oxford [redacted]

or visit our website at www.charttrials.abdn.ac.uk/ukuff

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Health Sevices Research Unit, University of Aberdeen, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD

Appendix 8 Two- and 8-week telephone assessments

UKUFF SHOULDER TRIAL 2 & 8 WEEKS POST-TREATMENT

Study ID: ☐☐☐☐☐ **C. TELEPHONE ASSESSMENT**

Today's date: (day/month/year) /____/____/20__. Telephone number_____

Good morning/afternoon Mr/Ms/Mrs_____

My name is _____ and I am working on the UKUFF shoulder study that you agreed to take part in.

I am phoning you today, just to ask you a small number of questions, which should take less than 5 minutes. ***Is now a convenient time for you? (Pause)*** *If not, I could ring you back later today - or tomorrow?*

IF NO - RECORD AGREED DAY/TIME TO CALL BACK:

date/day……. Time……..

IF YES, CONTINUE WITH INTERVIEW BELOW:

Good. I'm now going to start by asking you a few questions - all relating to your shoulder.

1. ***Within the last 24 hours……*****Have you been wearing a sling at all? Yes ☐ No ☐**

If no go to QU. 2 below

IF YES, Have you worn your sling for……. More than 12 hours? ☐

Between 6 and 12 hours? ☐

More than 3, but less than 6 hours? ☐

Or less than 3 hours? ☐

2. ***Within the last 24 hours……***

How would you describe the *worst* pain you had from your shoulder?

None ☐ Mild ☐ Moderate ☐ Severe ☐ Unbearable ☐

3. ***Within the last 24 hours……***

How much has pain from your shoulder interfered with your usual work *(including housework)*?

Not at all ☐ A little bit ☐ Moderately ☐ Greatly ☐ Totally ☐

4. **Were you troubled by pain from your shoulder in bed last night?**

No, not at all ☐ Yes, just at first ☐ Yes, during some of the night ☐ Yes, throughout the night ☐

Version 2 01/09/2007

5. ***Within the last 24 hours…….***
Have you taken any painkillers or anti-inflammatory drugs - <u>because of your shoulder?</u>

Yes ☐ **No** ☐

IF YES, 5a. could you tell me which types you have used? (within last 24 hours)

MEDICATION	Dose (mgs) OR NO. OF TABS	HOW OFTEN? (how many times)	BOUGHT 'over the counter' OR PRESCRIPTION

6. **During the last 2 weeks** (since your surgery/completion of Rest & Exercise Programme)**:**
Have you had any <u>additional</u> treatment (for example: injection into the shoulder, antibiotics or surgery) **<u>for your shoulder</u>?**

Yes ☐ No ☐ **IF NO, GO TO QUESTION 7**

IF YES, 6a. please tick all that apply:

Injection into the shoulder ☐ Surgery ☐ Antibiotics ☐

Any other unexpected treatment ☐ *please give details*……

IF 'any other treatment' included admission to hospital:

6b. What was the reason for your hospital admission?.....

IF this admission included surgery:

6c. What kind of surgery did you have?.....

6d. What was the name of the hospital?.....

6e. How many nights did you stay in hospital?.....

7. **What date were you discharged from hospital after your shoulder rotator cuff repair operation? ___/___/____ (dd/mm/yyyy)**

8. **Finally, could you tell me, are you currently employed?** **Yes** ☐ **No** ☐

IF YES, 8a. Are you currently 'off sick' or working reduced duties <u>because of your shoulder</u>?

Yes - 'off sick' ☐ Yes - working reduced duties ☐ No - working usual hours/duties ☐

Thank you very much. That is all I need to ask you today.

We will be in touch again.

Appendix 9 Eight-, 12- and 24-month questionnaires

8 Month Questionnaire

Study Number:

UK Rotator Cuff Surgery Trial

UKUFF

CONFIDENTIAL

UKUFF SHOULDER TRIAL

PATIENT ASSESSMENT

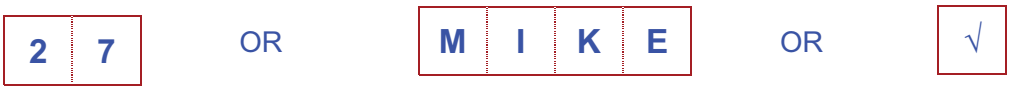
8, 12, 24 MONTHS POST RANDOMISATION

Thank you for helping us with our research into rotator cuff tears.
We would be very grateful if you could complete and return this questionnaire in the enclosed freepost envelope.

ISRCTN No: 97804283
Version 2 27/05/08

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:



Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions, we would like you to think about different time periods, such as during the last 4 weeks or during the last 8, 12, 24 months. Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

Thank you for your help.

Section 1 – Shoulder Problems And Treatments

Please tick ONE box for EACH question

2. **Have you been unwell for a reason other than your shoulder** *(during the past 8 months)***?**

Yes ☐ No ☐ **IF NO, GO TO QUESTION 3**

If YES, 2a. What was the reason? .....

.....

If YES, 2b. Were you admitted to hospital? Yes ☐ No ☐

If YES, 2c. Did you have an operation? Yes ☐ No ☐

3. **How are the problems related to your shoulder NOW, compared with 8 months ago** *(at the start of this study)***?**

Much better	Slightly better	No change	Slightly worse	Much worse
☐	☐	☐	☐	☐

4. **Overall, how pleased are you with your shoulder symptoms so far?**

Very Pleased	Fairly pleased	Not very pleased	Very disappointed
☐	☐	☐	☐

5. **Are you currently employed?** Yes No

If YES, 5a. Are you currently 'off sick' or working reduced duties because of your shoulder?

Yes 'off-sick'	Yes working reduced hours/duties	No working usual hours/duties
☐	☐	☐

Section 2 – Questions About Your Shoulder

Please tick ONE box for EACH question

During the past 4 weeks

1. How would you describe the worst pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
☐	☐	☐	☐	☐

During the past 4 weeks

2. Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

During the past 4 weeks

3. Have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

During the past 4 weeks

4. Have you been able to use a knife and fork - at the same time?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks …

Please tick ONE box for EACH question

During the past 4 weeks

5. Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

6. Could you carry a tray containing a plate of food across a room?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

7. Could you brush/comb your hair with the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

8. How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

During the past 4 weeks …

Please tick ONE box for EACH question

During the past 4 weeks

9. Could you hang your clothes up in a wardrobe, - using the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With great difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

10. Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

During the past 4 weeks

11. How much has pain from your shoulder interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

During the past 4 weeks

12. Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

Section 3 – Shoulder Pain and Disability

Please ring round ONE number to EVERY question where
0 = no pain and 10 = worst pain imaginable

PAIN SCALE DURING THE PAST WEEK

How severe is your shoulder pain ……

1. At its worst?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
2. When lying on involved side?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
3. Reaching for something on a high shelf?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
4. Touching the back of your neck?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable
5. Pushing with the involved arm?	No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable

Please ring round ONE number to EVERY question where
0 = no difficulty and 10 = so difficult required help

DISABILITY SCALE DURING THE PAST WEEK

How much difficulty do you have……

1. Washing your hair?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
2. Washing your back?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
3. Putting on an undershirt or pullover sweater?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
4. Putting on a shirt that buttons down the front?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help

Please ring round ONE number to EVERY question where 0 = no difficulty and 10 = so difficult required help

How much difficulty do you have……

5. Putting on your pants?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
6. Placing an object on a high shelf?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
7. Carrying a heavy object (more than 10 pounds)?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help
8. Removing something from your back pocket?	No difficulty	0	1	2	3	4	5	6	7	8	9	10	So difficult required help

Section 4 - Your General Health

State of Mind

Please tick ONE box for EACH question

1. How much time during the past month:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
b) Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
c) Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
d) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
e) Have you been a happy person?	☐	☐	☐	☐	☐	☐

Your Health Today

Please indicate which statement describes your own health state today.

Please tick ONE box for EACH question.

a) Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

b) Self-care

- I have no problems with self care ☐
- I have some problems with washing or dressing myself ☐
- I am unable to wash and dress myself ☐

c) Usual Activities

- I have no problems in performing my usual activities (eg: work, study, housework, leisure activity) ☐
- I have some problems in performing my usual activities ☐
- I am unable to perform my usual activities ☐

d) Pain / Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

e) Anxiety / Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Finally:

Date you filled in this questionnaire D D / M M / Y Y Y Y

THANK YOU

Thank you for completing this questionnaire. The information you have given us will be extremely useful.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the envelope provided.

Please could you inform us of any changes to your phone number:

And inform us of any changes to your contact details: .....

.....

.....

Thank you again for your help.

If you would like any further information or have any queries about the study, please contact:

The UKUFF Study Office in Aberdeen [redacted]

or visit our website at www.charttrials.abdn.ac.uk/ukuff

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Health Sevices Research Unit, University of Aberdeen, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD

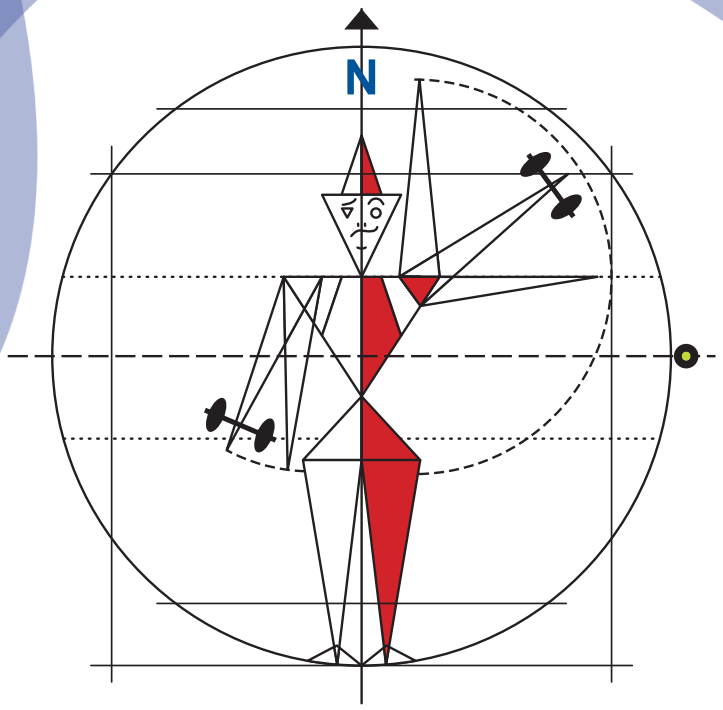
Appendix 10 Rest-then-exercise programme

UK Rotator Cuff Surgery Trial

UKUFF

REST THEN EXERCISE

Rest then exercise



This booklet will guide you through the Rest then Exercise programme.

This booklet was written by: Jane Moser (Clinical Physiotherapy Specialist – Shoulders) and Andy Carr (Nuffield Professor of Orthopaedic Surgery) with help from specialist physiotherapy colleagues (Dr Jeremy Lewis, Dr Bobbie Ainsworth and Jo Gibson).

Help and feedback was gratefully received from people with shoulder problems related to their rotator cuff muscles.

Design and Illustration: ***Oxford Designers & Illustrators***

Cover Illustration: ***Angela Walters***

FEBRUARY 2007 VERSION 1

www .charttrials.abdn.ac.uk/ukuff

REST THEN EXERCISE

Disclaimer:

The information contained here is intended solely for the general information of the reader, not intending to diagnose or take the place of professional medical care.

The information is neither intended to dictate what constitutes reasonable, appropriate or best care for people with rotator cuff tears of the shoulder, nor is it intended to be used as a substitute for professional medical care.

This programme was designed for use in the United Kingdom Rotator Cuff Surgery Trial (UKUFF) ISRCTN 97804283 for people with diagnosed rotator cuff tears and as yet, is unevaluated. All content, including text, graphics, images and the information contained within is general information.

It is unable to take into account unique person- specific issues. If you have persistent or worsening problems with your shoulder, please consult your doctor or physiotherapist to access individual medical advice and treatment options. The information in this programme is not a substitute for a medical assessment.

Contents

Introduction

You have a tear in your rotator cuff tendon(s). This is a very common problem which affects many people, especially over the age of 50. What is interesting is that many of your friends and family of a similar age may also have this tear and yet are NOT affected by a troublesome shoulder. A research study has shown that 28% of people over the age of 60 had a tear of the tendon, but reported no problems with their shoulder. We know that you have a tear and you ARE having problems with your shoulder.

This programme aims to

- decrease the pain
- increase movement
- increase strength

in your shoulder.

So, even though you still have a tear in your tendon, it does not cause a problem in your daily life. We know that these improvements are definitely possible, even when a tear has been found. Research studies have shown that people who have a tear in the tendon can have a satisfactory outcome without surgery. The Rest then Exercise Programme can be viewed as an extra treatment, of very low risk and some potential benefit.

This is a summary of the Rest then Exercise Programme

- 4 weeks of relative rest & modification of activities to reduce the pain
- 8-12 weeks of exercises to work all the muscles around your shoulder

The exercises are used widely and have been recommended by shoulder rehabilitation experts.

The first section of this booklet explains what the rotator cuff muscles are and do. It also includes frequently asked questions.

If you just want to know what we are suggesting you do, please go straight to page 5.

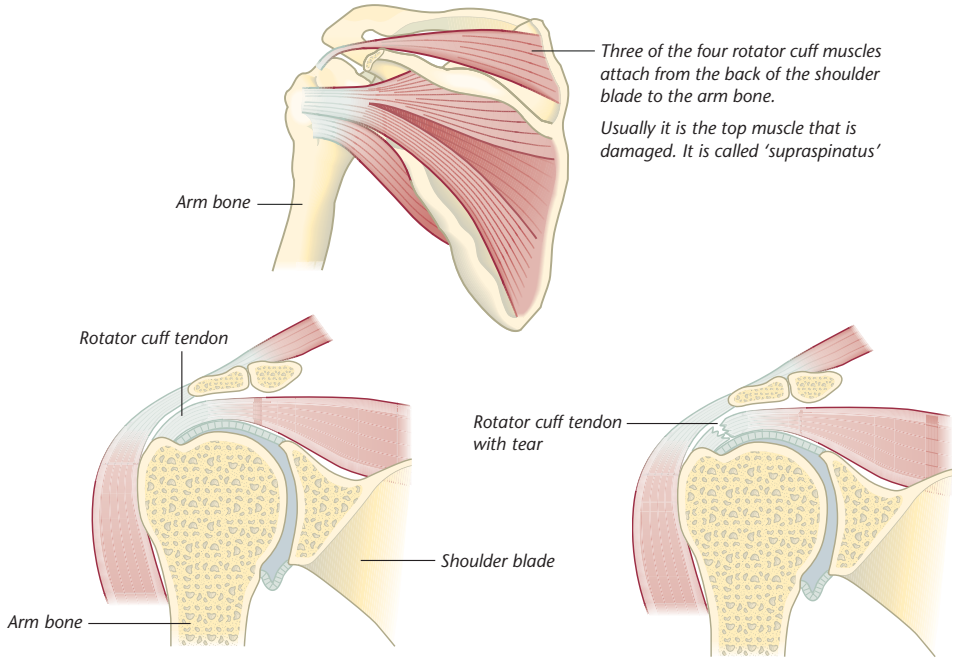
SECTION 1

Frequently asked questions

What are the rotator cuff muscles/tendons?

- They are a group of four deep muscles*, think of them as 'undercoat muscles'
- They attach from your shoulder blade (scapula) to the arm bone (humerus)
- They form a hood around the arm bone
- Commonly there is a problem with one tendon (supraspinatus)

**supraspinatus, infraspinatus, subscapularis and teres minor*



What do the rotator cuff tendons do?

Tendons connect your muscle to the bone

The four muscles work together and act like 'guy ropes', keeping the ball positioned well against the socket

- The rotator cuff muscles (and tendons) work when you take your arm away from your side and/or overhead
- They work harder when you are lifting or carrying a weight
- They work together with other muscles around your shoulder
- They work with 'overcoat' or 'outside' muscles to move your shoulder
- They stabilize the ball in the socket and help your power muscles to move your arm
- They work as a group together

What happens to the tendons as I get older?

- The supraspinatus tendon 'wears' with everyday life and may eventually split and tear
- This does not always lead to pain or loss of function
- Torn rotator cuff tendons are common with older age
- Not everyone with a torn tendon has problems with the shoulder
- The torn tendon does not repair itself
- There is a genetic link which means that some people are more at risk of developing this than others

If my tendon is torn, surely I will not be able to move my arm?

- There are people who have a tear in the tendon and can move their arm without pain or apparent weakness. We don't know why this is or what is different about them
- In fact many people over the age of 50 who do not have any pain or symptoms have torn tendons
- Your shoulder may improve with this simple programme
- There is absolutely no guarantee that you will have a reduction in pain or increase in strength or function following Rotator Cuff repair surgery
- Your arm may not be as strong as it used to be, especially when your arm is out to the side
- For some people this lack of strength can also remain after surgical repair (an operation)

If my tendon is torn, will it hurt until it is repaired?

- There does not always appear to be a direct relationship between the pain and a tear in the tendon
- A big tear does not mean you will have a lot of pain and many big tears cannot be repaired with surgery
- Some people can have a torn tendon and have little or no pain
- Pain can vary even though the tear in the tendon is present all the time
- Pain can stop muscles working so that your arm feels weaker still
- Pain can be eased with methods other than an operation (tablets, heat, injections, rest, exercise etc.)
- The Rest then Exercise Programme is a method of treatment and has been shown in at least ten research studies to be an effective way of reducing pain and increasing functional ability

The Rest then Exercise Programme

- 4 weeks of relative rest & modification of activities to reduce the pain
- 8-12 weeks of exercises to work all the muscles around your shoulder to compensate for the damaged tendon. The non-damaged muscles/tendons can be trained to take a greater 'share' of the work which may result in less pain and more movement and strength.

SECTION 2

Relative rest phase – 4 weeks

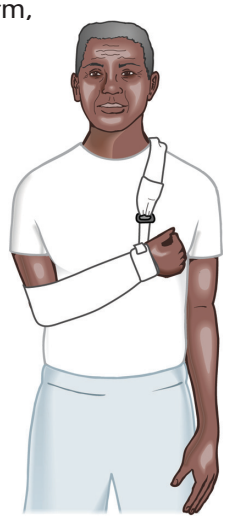
Some of the feeling of 'weakness' in the arm may be due to the pain 'stopping' the undamaged muscles working normally around the shoulder.

Therefore to start your treatment, we would like you to avoid doing things that make the pain worse. To begin this process, we would like you to give your shoulder a 'rest'.

This is also what we would advise you to do if you had an operation on your shoulder. It may be that resting the shoulder is an important factor in improving your symptoms.

We appreciate that this 'rest' for your shoulder will affect your ability to perform your normal activities, which may be very annoying!

However if the rest helps reduce the pain, you may then find it more comfortable to move your arm. This, in the long term, may help you with your daily tasks.



What to do

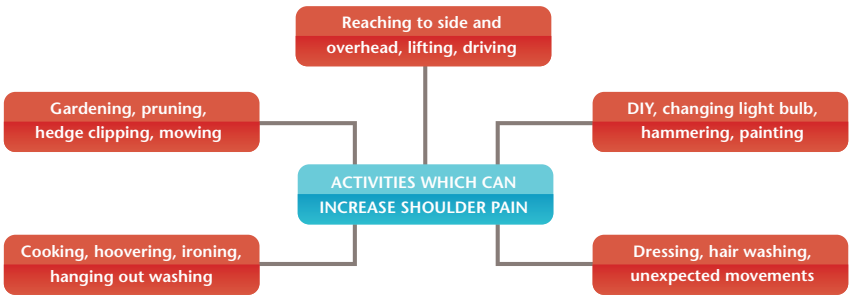
- We would like you to REALLY rest your shoulder for 4 weeks
- We want you to try and keep your pain levels as LOW as possible
- You can use a sling to help you do this (available at chemists or online).
- Make sure the weight of your arm is fully supported by the sling

When to wear the sling

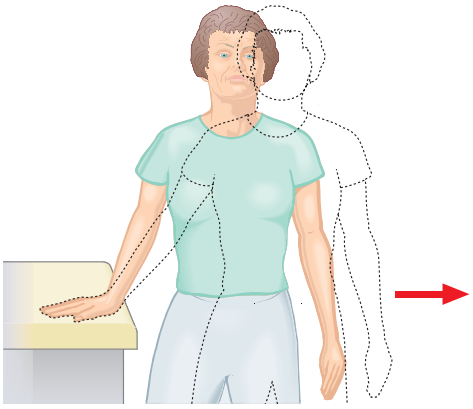
- Give your shoulder pain a score between 0–10
- Imagine a score where 0 is 'no pain' and 10 is the 'worst pain imaginable' in your shoulder
- If you taking medication think of your pain score while you are taking them

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst pain imaginable

- We would like you to AVOID all activities and movements that consistently increase your pain above 4
- Therefore we would advise you to wear the sling for activities that would increase your pain above 4
- If your pain is always above 4 then you need to wear the sling ALL DAY
- This may be a real nuisance but we would like you to do this for 4 weeks
- It may take 4 weeks for pain to settle down once you have stopped aggravating activities
- This MAY mean that you will NOT be able to do your usual activities!



- If the pain increases above 4 on the scale we would advise you to STOP or CHANGE the way you do that particular thing
- Usually the pain is worse when you reach with your arm, so try and avoid activities that involve this
- It may mean that you will have to move things that you use everyday to a lower height or closer to you
- Sometimes using a step can help raise you up but make sure you are safe!
- If possible, ask other people to do certain difficult tasks
- If moving your arm out sideways is painful (eg for washing armpit and putting on deodorant), try placing your hand (or elbow) on a surface and move your body away



Remember, it is just for four weeks to see if the pain will reduce with rest.

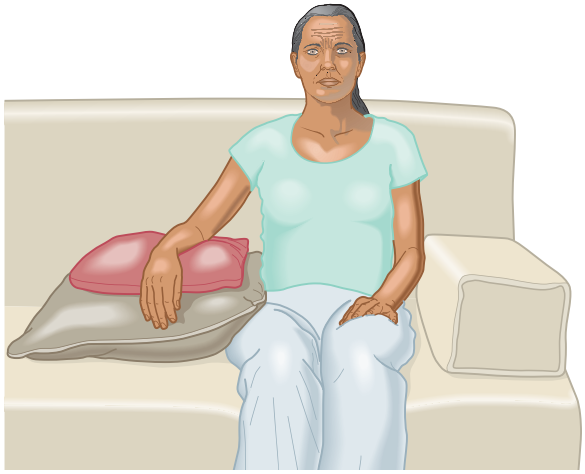
If you feel it would help, write down some things that often/usually make ***your*** shoulder pain worse. In the opposite column, record possible ways of avoiding the aggravating activities for the next four weeks.

Today's date is	4 weeks' time the date is .....
What things make my shoulder hurt?	**How can I do this differently or not at all?**

What to do at night/resting

- Take the sling off at night unless it is very helpful at this time
- Try different resting positions at night
  - When lying on your back, place a folded towel or pillow under your upper arm
  - When lying on your good side, place a pillow or two in front of you so that your arm cannot drop across your body

- When sitting, try propping your arm on a cushion



What else to do

- Research has shown a healthy diet may have an effect on tendon health and improve symptoms
- A healthy diet includes
  - reducing/stopping smoking
  - eating more fruit and vegetables (increases anti-oxidants)
  - increasing omega 3 essential fatty acid intake (eg.oily fish, flaxseeds, walnuts, kidney beans, winter squash)

Don't let the shoulder get stiff!

- Although we want you to rest the shoulder tendons, we do not want the shoulder to stiffen
- It may be easier to do the exercises with someone the first time The person can read the instructions whilst you try the actions

These are **gentle exercises** that we recommend you to do

Remember!

- The exercises do not make the muscle/tendon work hard
- The exercises should feel 'easy' and 'sliding' without the feeling of muscles working with effort
- **Do the exercises once or twice a day**
- Do not do them if it is a struggle
- Do not force the arm to move if it does not want to
- Do not let the pain rise over 4

All exercises are shown for the right arm.

Set A Keeping the shoulder moving – for four weeks

A1) Shoulder blade exercise

Sitting or standing

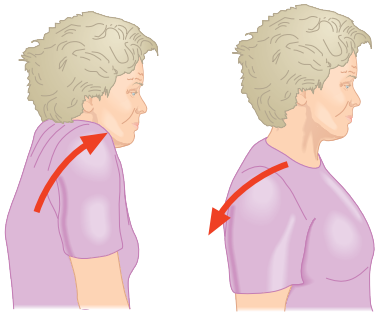
Keep your arms relaxed by your sides

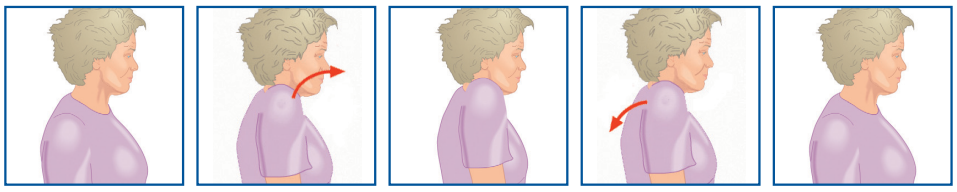
Shrug shoulders up and forwards

Roll shoulders down and back

Relax

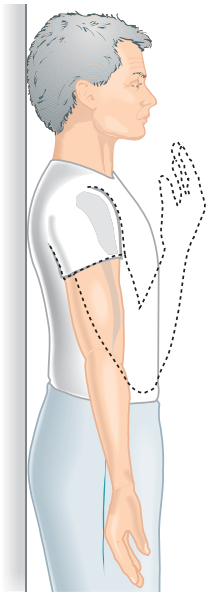
Repeat 5 times for each movement



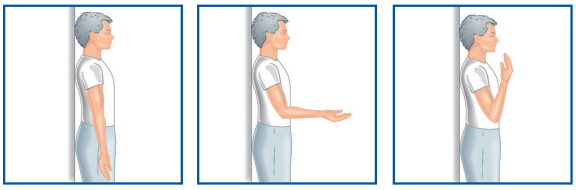


START FINISH

A2) Elbow exercise



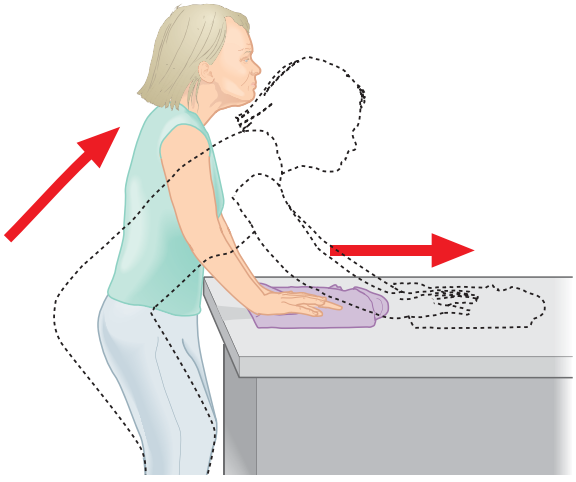
Standing
Straighten arm fully
Bend elbow so hand is coming towards shoulder
Repeat 5 times



START FINISH

A3) Shoulder elevation stretch

Stand facing a flat horizontal surface at waist height
e.g. table, work surface
Place both hands on a slippery towel, on the surface
Bend your knees and push your backside away from the table;
at the same time let your arms slide forwards
Then stand up again, sliding your hands back towards you
As you repeat, try and stretch forwards as far as you comfortably can
Repeat 5–10 times



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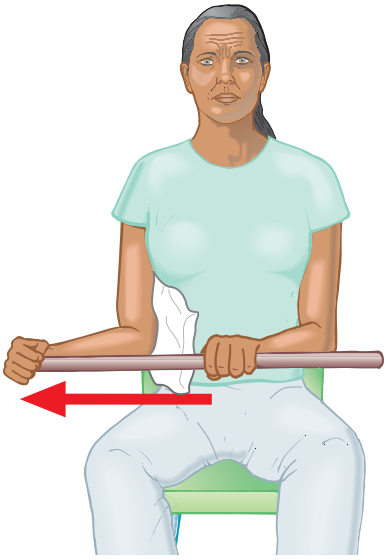
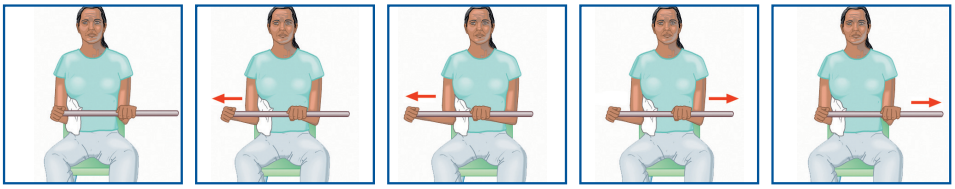




START FINISH

A4) Shoulder rotation stretch

Sit back in chair

Bend elbows to right angle

Place cushion/towel in-between elbow and waist on the bad shoulder side

Using both hands, hold a stick/umbrella/rolling pin

Using the stick, push your hand on the bad side outwards

Keep the elbow against the cushion/towel

Your hand should be now outside your elbow

Do the movement gently, use the stick rather than your muscles around the bad shoulder

Feel a stretch, hold the stretch for 20 seconds

Relax

Repeat 3–5 times

If the movement is painful rather than stretchy **DO NOT CONTINUE** with **THIS** exercise

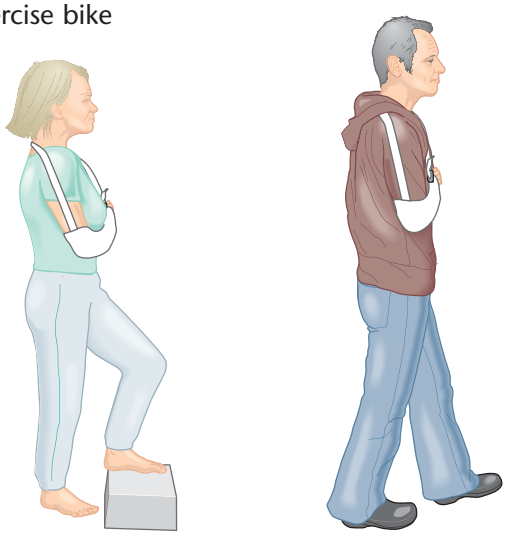
If you prefer you can do this lying down, with a folded towel under your upper arm

SET B General fitness exercises

There is evidence that general exercise can help reduce pain levels. Your ability will be dependent on your general health. Consult your GP if you are unsure of your suitability to exercise or if you experience any unusual symptoms during the programme. However, we would encourage you to remain as active as possible without increasing the shoulder pain above 4

If you are not usually active, here are some ideas

- Walking
- Step ups
- Standing up from a chair without using your arms (the lower the chair the more your legs work)
- Using an exercise bike



In all these activities you can wear the sling to keep the shoulder tendon/muscle relatively still.

- If you enjoy swimming,
  - still go to the pool
  - make your legs and body work
  - avoid arm movements if they increase your pain over 4

Please concentrate on RESTING the arm and doing these few maintenance/general fitness exercises for 4 weeks.

It may feel like a long time, but compared with the work and activity your muscle/tendon has done in your lifetime it is only a short rest!

AFTER 4 WEEKS
MOVE ON TO THE EXERCISES IN THE NEXT SECTION
Remember the date which will be

SECTION 3

EXERCISE PHASE – for twelve weeks

- After 4 weeks we would like you to start to exercise your shoulder muscles
- You can exercise in a lying (set C) or upright position (set D, sitting or standing)
- When you start these exercises, we suggest you try both set C and set D. There is no right or wrong exercise, try them and see which suits you
- The exercises are in a certain order (or progression), so that most people find the exercises at the beginning are easier than the ones at the end of each session
- **IF AN EXERCISE INCREASES YOUR PAIN ABOVE 4, THEN STOP THAT PARTICULAR EXERCISE**
- Do not do any exercise which makes the pain worse
- **Choose the exercise or position that is the LEAST painful for your shoulder and do THIS exercise daily**
- You may feel that your shoulder or arm muscles are working and the exercise feels 'hard work' or 'difficult to control'. When this happens the exercise is often helpful and we would encourage you to do it!
- Ideally we want you to find an exercise from those shown, which is relatively pain-free that you will be able to practise regularly
- If you find an exercise which you can do, and it becomes easier (which may take 6 weeks or longer) try the progressions that are suggested (e.g. light weights) or try an exercise in a different position. Please experiment with the exercises shown.
- Repetition rates are given as a guide only. You may well find that your muscles get tired and that you will have to build up the number of times you can do the exercise. For example start with 3–5 repetitions. Sensations of 'hard work', 'stiffness', uncomfortable' and muscle 'ache' are all expected and will tend to improve over 6–8 weeks
- Try to **do the exercises once every day**. You need to do them at least 4 times a week to make a change.
- All exercises are shown for the right arm

REST THEN EXERCISE

SET C LYING DOWN EXERCISES

You will need:

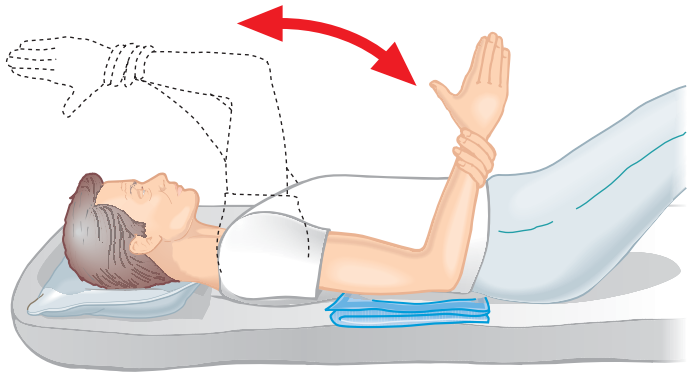
- A pillow
- A hand towel folded
- A weight (possibly) – see exercise C3

The first two exercises start with your arm up in a vertical position. You may have to find your 'own way' to get your arm into this position. If you cannot tolerate the vertical position – do not do THIS exercise.

Getting into the start position

Many people find this the easiest way to get into the start position

- Lying on your back with knees bent up, feet flat on the floor, pillow under your head
- Folded towel under your upper arm
- Use your good arm to lift your bad arm up in the air



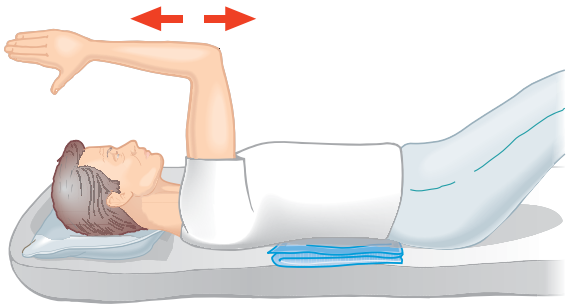
- Keep your bad arm as 'relaxed' and 'floppy' as possible. It will feel heavy to lift!
- When your upper arm is vertical, still support your bad arm but bend the elbow, you are ready to start!

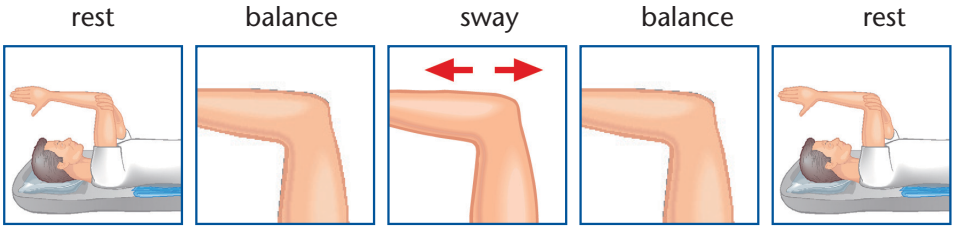
Note: If you have problems with both sides you may find getting into this start position difficult. If you cannot support your bad arm with the other, as both hurt or are weak, move on to the exercises in the next section (Set D), page 18.

C1) Balancing exercises

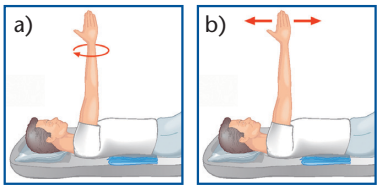
1. Try and keep this position (elbow of the bad arm bent (90°) and upper arm vertical), as you let go with the other hand
2. Balance the arm in this position, using your muscles
3. Sway your elbow gently up and down
4. Rest the shoulder muscles by holding the bad arm with your other hand again
5. Aim to repeat this balancing, swaying movement 10 times and build it up to do 3 sets (i.e. 30 repetitions in total)

If this arm position is painful, try with your hand nearer the opposite ear! Try and find a position/angle which does not increase the pain.



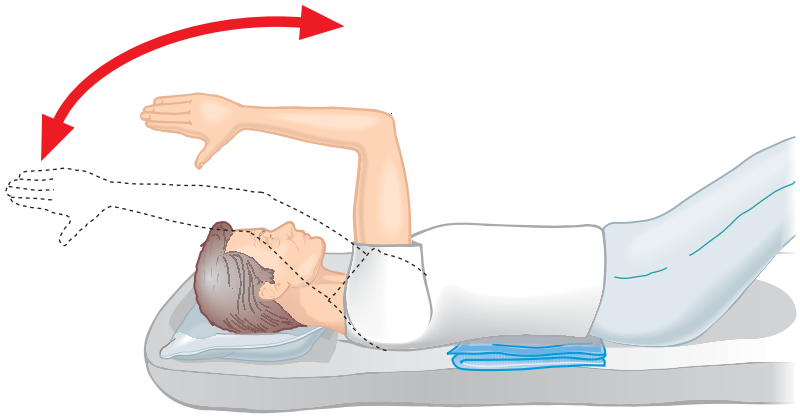


6. Progress this exercise by
   a) straightening your arm and moving your arm in small circles
   b) trying the swaying movement with your elbow straight

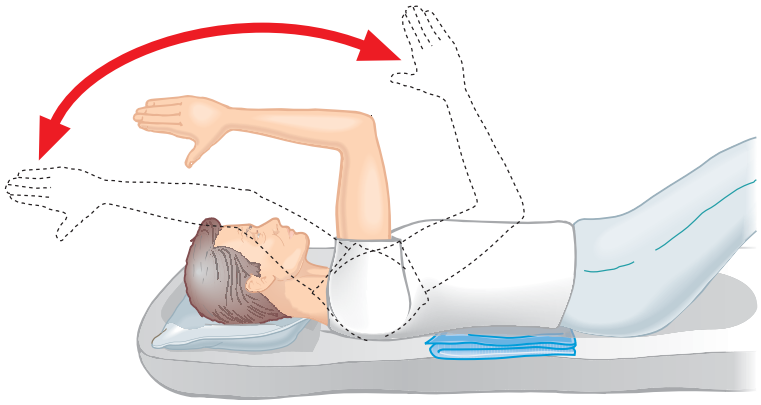


C2) Controlling your arm moving

1. Get into the start position (see above), let go with good arm
2. Move the elbow so you are trying to reach up overhead, towards the pillow
3. You may only be able to move a small amount to begin with
4. Keep the pain below 4
5. Allow your arm to straighten as it moves overhead
6. **You may need to experiment with your elbow or hand in different positions to find the 'painless route' or 'best route' for YOU to get your arm overhead**. There is not a right or wrong way. If you find a way to get your arm up overhead - do that!
7. Then return your arm back to the vertical start position with elbow bent or straight
8. Aim to repeat this 10 times and build it up to do 3 sets (i.e.30 repetitions in total)

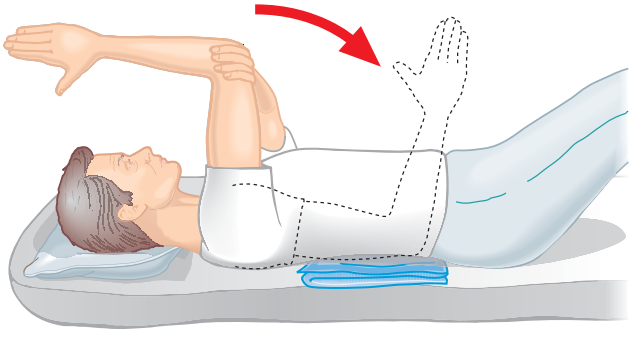


9. Progress this exercise by
   a) Gradually lowering your arm, with elbow bent, back down towards your side
   b) Eventually you may be able to touch the folded towel with your elbow and stretch up overhead again



START FINISH

Note: If it is painful to lower your arm towards the folded towel, try this trick. If possible, place the hand of your good arm, under the elbow or grip your wrist. When you start to lower your arm, resist the movement with your good arm so that you are pushing down against the good arm, rather than just lowering. If this helps, continue to do the exercise using this trick. Over time you may find that you can reduce the resistance and eventually you can imagine you are pushing down against something.



START FINISH

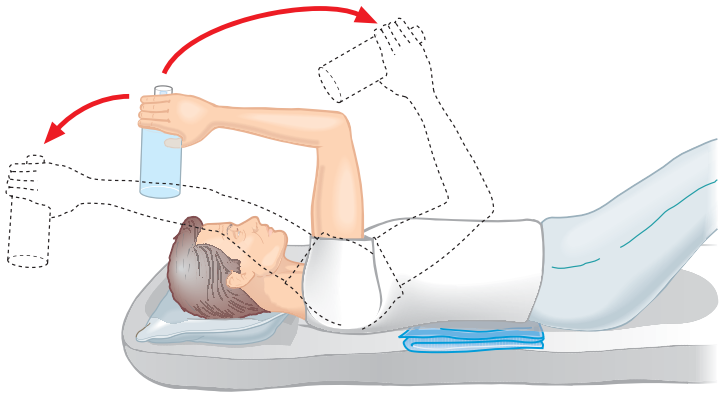
C3) Controlling your arm moving with a weight

1. If exercise C2 becomes easy, progress it by holding a weight in your hand
2. Choose a weight that you can control (e.g. start with 100g or 1lb)
3. Gradually increase the weight, but always keep the pain less than 4
4. You may be able to build this to 1.5 kg (3lbs 5oz).

Suitable things to use for weights include 0.5 litre plastic water bottles (with different amounts of water in), sealed bags of rice etc.
n.b. 0.5 litres = 500gms/1lb 2oz.

Small hand-held weights can be bought from sports shops and retail outlets.

Please be careful and make sure that you use something that you can grip safely.



START FINISH

SET D STANDING & SITTING EXERCISES

These two exercises are similar. Try them both and choose which you prefer or find easier to do in your daily routine. It will also be fine to do both.

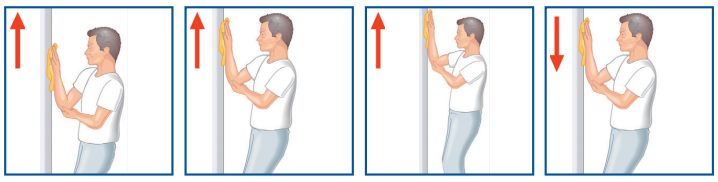
D1) Regaining arm movement while standing

You will need a

a) 'blank' wall or back of a door that you can stand close to. Ideally it needs to have a smooth surface

b) drying-up cloth or small towel – something slippery or which will slide

1. Stand facing the wall/back of the door
2. Using your bad side take a cloth/towel and place it against the wall/door
3. Now slide your arm up the wall supporting it with your other hand
4. Bend your knees a little and then straighten them as you **HELP** the bad arm slide up the wall with the good one
5. Stretch up as high as you comfortably can
6. Then slide the hands down
7. Keep the hand in contact with the wall all the time
8. Give as much help as is needed to make the movement seem smooth and relatively easy. Do **NOT** struggle
9. If it is painful lowering your arm, try resisting the movement so that you are **PUSHING** down against the pressure of the other arm. If this reduces the pain continue doing this. Over a period of weeks you may find that you can gradually reduce the amount of resistance you are giving
10. Repeat 10 times and build it up to do 3 sets (i.e. 30 repetitions in total)



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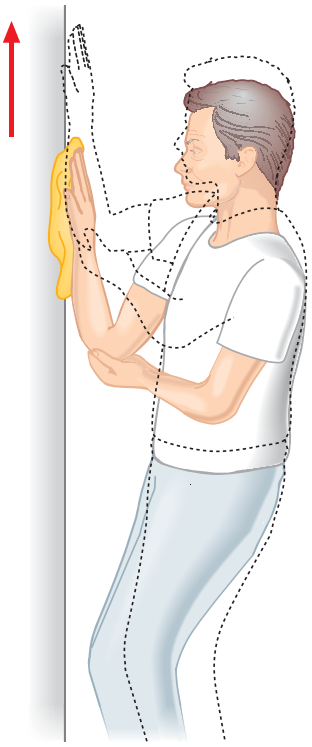
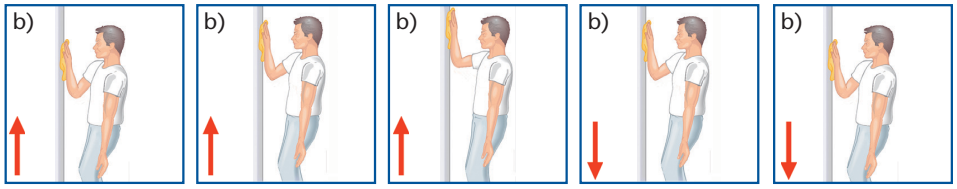


11. Progress this exercise by
    a) Reducing the help given by your good arm
    b) Eventually try and slide your arm up and down the wall by itself
    c) Lifting your hand off the wall when the arm is overhead



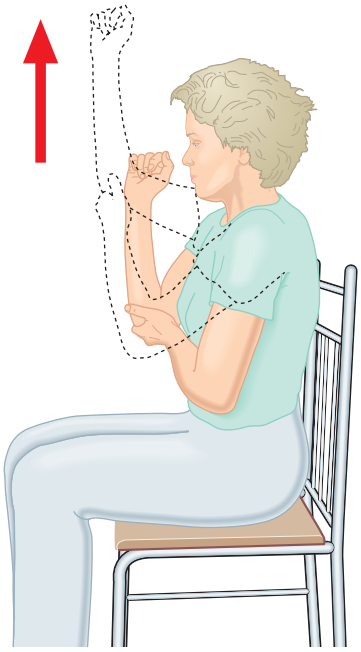
START FINISH

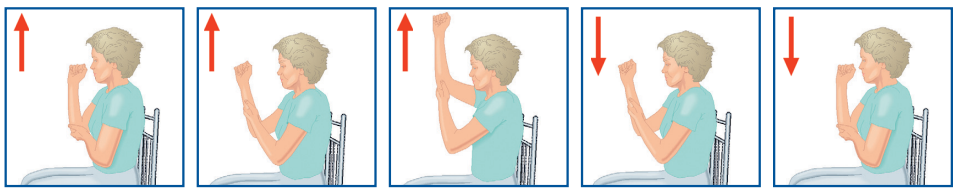
D2) Regaining arm movement while sitting (or standing)

You can sit or stand for these exercises. (If you stand make sure you do not 'cheat' too much by leaning back or over-arching your back.) If you do these exercises sitting down, you will need a firm chair (kitchen type).

If you get low back pain, or feel unsteady on your feet, we suggest that you do these exercises sitting down.

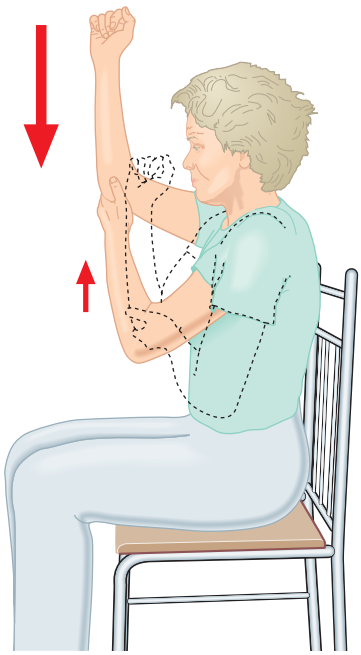
1. Support the elbow or wrist of your bad arm with the good
2. Start with your elbows bent and then stretch your arms overhead
3. Help support the weight of the bad arm as you lift
4. Lower your arm bringing your elbow into your side
5. If able, gradually reduce the amount of help (on the way up) you are giving with the other arm
6. **Try and 'find the painless route' with your elbow or hand at slightly different angles**
7. You are aiming to move the bad arm up and down without needing both arms

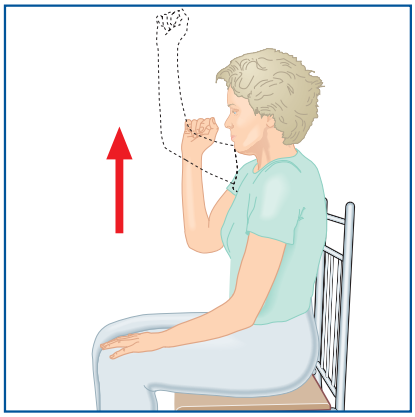


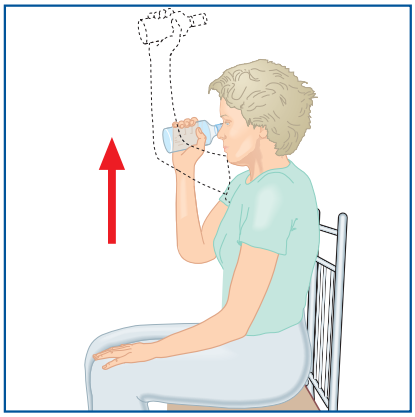


START FINISH

8. Then build the repetitions to 10 times, 3 sets
9. 'Tricks' to try:
   - lifting the elbow first then straightening the arm
   - doing the movement fast (almost like you are throwing your elbow forwards and up).
   - If it is painful lowering your arm, try resisting the movement so that you are **PUSHING** down. If this reduces the pain continue doing this. Over a period of weeks you may find that you can gradually reduce the amount of resistance you are giving
10. To progress this exercise
    a) Add a small weight and continue the exercise
    b) You may find there is a point beyond which you cannot increase the weight. Stop when you get to this stage.







Using your arm for daily activities

We hope that this programme will have eased the pain and improved movement and strength in your shoulder. Use your arm for daily tasks but avoid things that 'stir-up' your pain. You may still have several restrictions and may need to continue to modify your lifestyle. However this result may be the best you can achieve. You have taught your 'over coat' muscles to compensate to the best of their ability. You may find that you do not need to keep doing the exercises. If you have found them helpful, keep this information in a safe place for future use.

Appendix 11 Original trial protocol

UKUFF STUDY

The Clinical and cost- effectiveness of surgical (arthroscopic or open) versus Rest then Exercise management for tears of the rotator cuff.

PROTOCOL

A UK Collaborative Study funded by the
NHS HTA Programme

Version 2 08 September 2008 1 ISRCTN97804283

CONTENTS PAGE

PROTOCOL SUMMARY

AIM

To assess the clinical and cost effectiveness of three forms of management of rotator cuff tears – arthroscopic surgery, open surgery and a non-surgical/conservative treatment.

DESIGN

Multi-centred, parallel group, randomised control trial

PATIENT ELIGIBILITY

Full thickness, degenerative rotator cuff tear
Tear diagnosed by MRI or Ultrasound scan
Tear suitable for surgical repair
≥50 years old with the ability to consent

RECRUITMENT

The eligibility of the patients will be assessed by the consultant orthopaedic surgeon, with full consent being obtained either locally by a research nurse or remotely by the study office in Oxford. The aim would be to recruit over 600 patients from 70 centres throughout the United Kingdom.

INTERVENTIONS

Open surgery
Arthroscopic surgery
Rest then Exercise Programme

OUTCOME ASSESSMENT

Telephone questionnaire at 2 and 8 weeks post treatment
Postal questionnaire at 8, 12 and 24 months post randomisation
MRI scan at 12 months post surgery (for those randomised to surgical arm only)

ORGANISATION

Local: by Consultant Orthopaedic Surgeon
Central: by Study Office in Oxford (clinical co-ordination and health economic evaluation) and Study Office in Aberdeen (data entry and statistical analysis)
Overall: by the UKUFF Management Group and overseen by the Trial Steering Committee and the Data Monitoring Committee

FUNDING NHS Health Technology Assessment Programme
Start date: July 2007
Planned finish date: June 2012
Planned reporting date: July 2012

UKUFF PERSONNEL

Grant Holders

Andrew Carr, Raymond Fitzpatrick, Alastair Gray, Jill Dawson, John Norrie, Marion Campbell, Craig Ramsay, Jonathan Rees and Jane Moser

UKUFF Management Group
Andrew Carr, Raymond Fitzpatrick, Alastair Gray, Jill Dawson, John Norrie, Marion Campbell, Craig Ramsay, Jonathan Rees, Jane Moser, Alison McDonald, Gladys McPherson, Jonathan Cook, Cushla Cooper and Suzanne Breeman

Trial Steering Committee Independent Members
Chair Jeremy Fairbank, Professor of Orthopaedic Surgery, Oxford
Others Jo Gibson, Physiotherapist, Liverpool
Dair Farrar-Hockley, patient representative, Oxford

DataMonitoring Committee Members
Chair Roger Emery, Reader in Orthopaedic Surgery, London
Others Jeremy Lewis, Reader in Physiotherapy, London
Richard Morris, Senior Lecturer in Medical Statistics, London

UKUFF Study Team in Oxford
Andrew Carr, Raymond Fitzpatrick, Alastair Gray, Jill Dawson, Jonathan Rees, Jane Moser, Cushla Cooper and Claire Pumfrey

UKUFF Study Team in Aberdeen
John Norrie, Marion Campbell, Craig Ramsay, Alison McDonald, Gladys McPherson, Jonathan Cook, Suzanne Breeman and Margaret MacNeil

Other Information
International Standard Randomised
Controlled Trial Number (ISRCTN) ISRCTN97804283
REC Reference Number 07/Q1606/49
REC Version Number Version 1, April 2008
HTA Project Number 05/47/02

The clinical and cost-effectiveness of surgical (arthroscopic or open) versus Rest then Exercise management for tears of the rotator cuff

This protocol describes a major multi-centre UK trial to assess the clinical and cost effectiveness of arthroscopic surgery, open surgery and a Rest then Exercise program in the management of rotator cuff tears. For the surgical arms the surgeons will undertake their usual and preferred surgical techniques while the conservative management arm will comprise of a month of rest and then up to 12 weeks of specialised shoulder exercises. This conservative programme has been designed specifically for the trial with the help of consumers, physiotherapists and shoulder surgeons.

The eligibility of the patient will be assessed by the local consultant orthopaedic surgeon, with consent being obtained either locally by a research nurse or remotely by the study office in Oxford. Only when the consent form and the baseline questionnaire are returned will the participant enter the trial and be randomised to one of the three management arms. The patients will continue to be followed up at 2 and 8 weeks post treatment and 8, 12, and 24 months post randomisation.

1. BACKGROUND OF ROTATOR CUFF TEARS AND TREATMENT

In 2000, an assessment of the prevalence and incidence of consultations for shoulder problems in UK primary care (based on a three year longitudinal study of over 650,000 patients aged 18 and over) estimated the annual prevalence to be 2.4%, with the rate increasing linearly with age1. In addition, it is estimated that disorders of the rotator cuff account for between 30 and 70% of the shoulder pain cases that are reported2,3.

1.1 The problem

The clinical evidence available, regarding both the natural history and management of rotator cuff tears, is limited and conflicting4,5,6,7,8,9,10,11. Most reports are small scale, (<50 cases), single centre, retrospective cohort studies.

In one recent report, the surgical management of rotator cuff tears was reviewed by Dunn *et al*12. They surveyed members of the American Academy of Orthopaedic Surgeons (AAOS) and found there to be considerable variation in their surgical decision making. This included the type of surgery, the surgical techniques (for example, use of anchors, and type of suture) and also the type and duration of conservative treatment (including cortisone injections, physiotherapy, rest, advice, and analgesia and home exercises). They also found that higher volume surgeons were generally less enthusiastic about conservative care.

1.2 Treatment for rotator cuff tears

Rotator cuff tears can be treated both surgically (arthroscopic and open) and nonsurgically (for example by injection and exercises). In the UK there is wide variation in the treatment practice for rotator cuff tears and it is unclear which approach provides the best results for the patient.

1.2.1 Treatment by surgery

A rotator cuff repair operation aims to re-attach the tendons to the bone. The repair involves sewing the torn tendon into a groove on the bone, releasing a ligament and excising a

prominence on the bone (sub-acromial decompression) to give the repaired muscle more space in which to move.

In general three approaches are available for surgical repair. These include:

(a) Open
Open surgery involves the rotator cuff being repaired under direct vision (through an incision in the skin). During this procedure the deltoid muscle in the shoulder is detached from the bone.

(b) Mini-open
Mini-open surgery is an arthroscopically assisted repair. The sub-acromial decompression is performed arthrscopically and the repair is performed under direct vision (through a longer incision in the skin). During this procedure the deltoid muscle is split but not detached from the bone.

(c) Arthroscopic
Arthroscopic surgery involves both the sub-acromial decompression and the repair being performed through arthroscopic portals inserted into the shoulder.

For the purposes of the UKUFF trial, the open and mini-open surgical techniques are classified together as open surgery.

1.2.1.1 Arthroscopic v open surgery

Proponents of arthroscopic rotator cuff surgery suggest that the procedure may have advantages over standard open procedures in terms of less trauma to shoulder muscles (smaller incisions and theoretically less soft tissue damage), less post-operative patient discomfort together with decreased morbidity and early return of movement. The success of the repair, however, depends on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open surgery. Other potential disadvantages of the arthroscopic approach include increased technical difficulty and longer time in theatre. Only a few, small, randomized controlled trials directly compare procedures and, therefore, there is a need to compare the outcome of the two surgical techniques13.

1.2.2 Non-surgical treatment

In 2007 a systematic review was conducted by Ainsworth and Lewis14 to review the evidence for the effectiveness of therapeutic exercises for the treatment of full thickness tears of the rotator cuff. They concluded that there was some evidence to support the use of exercise in the management of full thickness rotator cuff tears but that there was a definite need for a well planned randomised controlled trial to investigate this further.

2. STUDY DESIGN

2.1 Aim

The aim of this study is to assess the clinical and cost effectiveness of arthroscopic surgery, open surgery and a Rest then Exercise program in the management of rotator cuff tears. There are two complementary components:

A A parallel group randomised controlled comparison of three forms of management of Rotator Cuff injuries (arthroscopic surgery, open surgery, and Rest then Exercise management), to assess their relative clinical effectiveness.

B An economic evaluation of these three forms of treatment to compare the cost effectiveness of the three management policies, to identify the most efficient provision of future care, and to describe the resource impact that various policies for rotator cuff repair would have on the NHS.

2.2 Design

A detailed survey of 126 surgeons from the British Elbow & Shoulder Society (BESS), carried out in preparation for this study, showed that the majority of surgeons practice only open surgery for rotator cuff repairs. A number of surgeons did indicate a willingness to randomise between arthroscopic and open surgery although the majority showed no equipoise for the two different techniques. Reflecting this lack of individual uncertainty around certain comparisons, randomisation will be organised within three strata depending on the surgeons' preparedness to randomise. The three strata are:

StratumA	arthroscopic surgery versus open surgery versus Rest then Exercise
StratumB	arthroscopic surgery versus Rest then Exercise
StratumC	open surgery versus Rest then Exercise

3. TRIAL RECRUITMENT

3.1 Surgeons eligibility

The study will require a 'minimum level of expertise' for the types of surgery undertaken. For both surgical techniques only consultant orthopaedic surgeons with a minimum of two years experience in consultant practice can participate. For those surgeons performing arthroscopic surgery, only those who have been trained to the levels defined by the education committee of BESS will be eligible. As such training standards do not exist for open surgery, only those who perform a minimum of 5 cases per year will be considered. The participating surgeons will represent a crosssection of high, medium and low volume practitioners undertaking both arthroscopic and open surgery.

3.2 Patient eligibility

3.2.1 Inclusion criteria

The patient must satisfy all the following criteria to be eligible for the study:

· Aged over 50 years
· Suffer from a degenerative rotator cuff tear
· Have a full thickness rotator cuff tear
· Rotator cuff tear diagnosed using MRI or Ultrasound scan
· Patient able to consent

3.2.2 Exclusion criteria

The patient may not enter the study if ANY of the following apply:

· Previous surgery on affected shoulder
· Dual shoulder pathology
· Significant problems in the other shoulder

· Rheumatoid arthritis/Systemic disease
· Significant osteoarthritis problems
· Significant neck problems
· Cognitive impairment or language issues
· Unable to undergo an MRI scan for any reason

Although there is no formal age limit, it is expected patients aged 85 years and over might not be eligible to participate.

Patients are free to withdraw at any time without consequence to the health care they receive.

3.3 Recruitment

Patients attending out-patient clinics with a rotator cuff tear diagnosed using either an MRI scan or an ultrasound scan, which is deemed suitable for surgical repair, will be approached. The patient must also have agreed to be placed on the NHS waiting list for surgery.

3.3.1 Remote recruitment

In most of the clinical centres, recruitment of the participants will be a two-step process. The patient's eligibility will be assessed by the local consultant orthopaedic surgeon who will introduce the trial to the patient using the prompt sheet and complete an eligibility check-list (Appendix I). If the patient is interested then the surgeon will provide them with a copy of the Patient Information Sheet (PIS Appendix I), which summarises what the study involves and answer any questions they may have.

If the patient is willing to enter the trial then the initial consent form (Appendix I) will be signed, which allows the patients details to be forwarded to the study office in Oxford. The office will then issue an invitation letter (Appendix II), the full Patient Information Sheet (Appendix I), a full consent form (Appendix I), a baseline questionnaire (Appendix IV) and a pre-paid return envelope to the participant by post, encouraging them to contact the office or their surgeon if they have any further questions or concerns. Patients who have not returned their questionnaire and consent form within a week will be telephoned by a member of the UKUFF team in Oxford. This contact will allow the patient to ask questions about the study and allow the team to assess if the patient is still willing to participate. When the full consent form and baseline questionnaire have been returned to the Oxford office the patient will then officially enter the trial and be randomised to one of the management programmes. A copy of the signed consent form will be returned to the patient. It is anticipated that some surgeons will have an extended scope practitioner or a research nurse working with them to help with this initial consenting process. Under these circumstances the participants may receive the invitation letter, the full Patient Information Sheet, a full consent form, a baseline questionnaire and a pre-paid return envelope from the clinical centre to return to the study office in Oxford.

3.3.2 Local recruitment

At some of our clinical centres a research nurse is available to complete the full consent process. The eligibility of the patient will initially be assessed by the local consultant orthopaedic surgeon who will introduce the trial to the patient using the prompt sheet and complete an eligibility check-list. If the patient is interested a research nurse will provide

them with a copy of the Patient Information sheet, which summarises what the study involves and answer any questions they may have.

The research nurse will organise a time for the patient to come back in to the clinic to sign the full consent form and complete the patient assessment form. The patient will also receive a baseline questionnaire to complete at home and return to the study office in Oxford. When these details have been returned to the study office in Oxford the patient will officially enter the trial and be randomised to one of the management programmes. A copy of the signed consent form will be returned to the patient.

3.4 Randomisation procedures

When the full consent form and the baseline questionnaire have been received by the study office in Oxford the participant will be randomised to one of the management programmes. Randomisation will be by computer allocation using the service provided by the Health Services Research Unit, University of Aberdeen. Allocation will be stratified by the surgical technique performed by the surgeon (open and/or arthroscopic) and minimised using centre, age and size of tear. After randomisation the participant is considered irrevocably part of the trial for the purpose of the research, irrespective of what occurs subsequently.

3.4.1 Randomisation to surgical arm

The study office in Oxford will send an allocation letter to the participant (Appendix II), detailing the surgical procedure they have been randomised too, along with the Post Operation Guideline Booklet (Appendix II) (unless instructed otherwise by the local consultant surgeon). The consultant surgeon and the participants GP (Appendix II) will also receive letters outlining which surgical procedure their patient has been randomised too. It is expected that the intervention will be undertaken within four months of randomisation.

The participating surgeon will be expected to perform the type of surgery that the patient has been randomised to. Details of the surgical technique used (including method of repair and theatre equipment used e.g. types of suture) will be recorded, as well as the size of the tear, the appearance of the tendons involved, the ease of repair and the completeness of the repair (Appendix IV). If circumstances dictate that the allocated surgical technique can not be carried out then an alternative procedure should be conducted, in accordance with the UKUFF intention to treat principle. The surgeon is also asked to contact the study office if their patient is unwilling or unable to have the operation on the arranged date.

3.4.2 Randomisation to conservative arm

The study office in Oxford will send an allocation letter to the participant along with an information pack containing a self-help CD, self-help booklet and a sling (Appendix II). The participants will be asked if they have access to a DVD player or computer, although the information contained on the CD is identical to the information in the booklet. To ensure the participants receive the information pack, a reply slip will be enclosed with the pack asking the participants to check the contents and then return the slip to the study office in Oxford. The consultant surgeon and the participants GP will also receive letters outlining that their patient has been randomised to the conservative management programme (Appendix II). All participants randomised to the conservative arm will receive the same information and advice. If they require further information about non-surgical care they will have access to a

telephone free-call help-line where clinical staff and/or the research physiotherapist will be available to answer questions and provide advice. The patients GPs will also be asked to inform the study office if the patient consults them regarding any physiotherapy treatments. This information is important as attending a physiotherapy session may alter the outcomes of the programme and so all sessions need to be documented.

The Rest then Exercise participants will be placed on the NHS waiting list for surgery at the same time as the surgical arm participants. Due to the length of most of the Trust's NHS waiting lists, they should be able to complete the Rest then Exercise programme before they would be due for surgery. However, it is anticipated that a few participants may have their date of surgery delayed while they complete the programme, although this is not anticipated to be a regular occurrence. Surgeons are asked to contact the study office if their patients decline surgery after the completion of the Rest then Exercise Programme.

4. DATA COLLECTION AND PROCESSING

Outcome assessments are primarily from patient based questionnaires and the 12 month post surgeryMRI scan.

4.1 Questionnaires

A combination of the Oxford Shoulder Score (OSS), the shoulder pain and disability index (SPADI), the mental health inventory (MHI-5) and the EQ-5D will be used to assess functional outcome and patient quality of life. These will assess a range of symptoms often experienced with rotator cuff tears e.g. pain, weakness and a loss of function. Outcome assessment is conducted by participant self-completion questionnaires and as such, interviewer bias and clinical rater bias is avoided. This form of outcome measurement has consistently performed well in comparison to clinician based assessments and general health status measures. All participants, including those who have withdrawn from their allocated intervention but who still wish to be involved in the study, will be followed up, with analysis based on the intention to treat principle.

Participants will receive questionnaires at the following time points (Appendix IV):

- Baseline questionnaire – completed before randomisation
- 2 and 8 weeks post treatment – questionnaire completed over the phone and includes a conservative programme compliance questionnaire if applicable
- 8, 12 and 24 months post randomisation

The baseline, 12 and 24 month post randomisation questionnaires will also incorporate a cost-effectiveness analysis. Questions relating to information on primary care consultations, other consultations, out-of-pocket costs and work-impact of the intervention received will be included.

The study office in Aberdeen will contact participants whose questionnaires have not been returned. In the first instance this will be through a reminder letter by post or email, depending on the participant's preference (Appendix III). If the questionnaire is still not returned by the specified time-frame, the study office in Aberdeen will telephone the participant and address any administrative issues that may have arisen, such as change of address, loss of questionnaire. If any clinical issues are identified the study office in Oxford

will contact the participant, if appropriate, and address these issues. The time period allocated to the follow-up checks will depend on which outcome assessment it relates to.

4.2 MRI scan

A number of authors have reported high rates of re-rupture of the rotator cuff tear (20-54%) after surgery, with some reporting a significant correlation between re-rupture and poor outcome15. In addition, MRI scanning has been shown to have high sensitivity and specificity (85-95%) in the detection of full thickness tears16. For these reasons, participants randomised to surgery will be asked to have an MRI scan at 12 months post operation to assess the state of the rotator cuff repair. These will take place locally and will be arranged by the study office in Oxford, at a time agreed to by the Trust and the participant. The MRI scans will be collected centrally and read by an independent consultant radiologist who is unaware of the type of surgery that was performed. Any re-tears will not be reported to the participating surgeons, so as not to deviate from their normal practise. However, if patients represent to surgeons with symptoms of a re-tear, the surgeon may contact the UKUFF office in Oxford to ask for the MRI scan results. Incidental abnormalities will be routinely reported to the
surgeon.

5. ANALYSIS

Statistical analyses will be based on all people randomised, irrespective of subsequent compliance with the randomised intervention. The principal comparisons will be:

i. all those allocated arthroscopic surgery versus all those allocated rest and exercise (Strata A & B)
ii. all those allocated open surgery versus all those allocated rest and exercise (Strata A & C)
iii. all those allocated open versus all those allocated arthroscopy surgery (Strata A, B & C)

5.1 Measure of outcome

The primary outcome measure is:

- Oxford Shoulder Score at 24 months after randomisation

The primary measure of cost effectiveness is:

- Incremental cost per quality-adjusted life years

Secondary outcome measures include:

- Oxford Shoulder Score at 12 months after randomisation
- Eq-5d at 12, 24 months after randomisation
- MHI-5 at 12, 24 months after randomisation
- Shoulder pain and disability index (SPADI) at 12, 24 months after randomisation
- Participant's pleasure with shoulder symptoms at 12, 24 months after randomisation
- Participant's view of state of shoulder at 12, 24 months after randomisation
- Surgical complications (intra and post-operative) at 12, 24 months after randomisation
- Economic outcomes

The way in which this data will be analysed is set out in Appendix V (Dummy Tabulations).

5.2 Planned subgroup analyses

(i) Size of tear (small versus medium/large);
(ii) Age <65 or ³65;

Stricter levels of statistical significance (2p<0.01) will be sought, reflecting the exploratory nature of these subgroup analyses.

5.3 Statistical analysis

Reflecting the possible clustering in the data, the outcomes will be compared using multilevel models, with adjustment for minimisation variables and participant baseline values. Statistical significance will be at the 2.5% level with corresponding confidence intervals will be derived. All participants will remain in their allocated group for analysis (intention to treat). Comparisons (i) and (ii) will be based upon the respective direct randomised evidence only. For comparison (iii), a meta analysis will be used to combine the results from the direct comparison (using stratum A) and an indirect comparison (using strata B and C). A secondary analysis will investigate the impact of surgical expertise level (learning curve effects)17. All study analyses will be according to a statistical analysis plan that will be agreed in advance by the Trial Steering Committee. A single main analysis will be performed at the end of the trial when all follow up has been completed. An independent Data Monitoring Committee (DMC) will meet early in the trial to agree its terms of reference and other procedures and will review confidential interim analyses of accumulating data at least annually as directed.

5.4 Economic evaluation

A cost-effectiveness analysis will be performed. A simple patient cost-related questionnaire will be sent out at baseline and at 12 and 24 months post randomisation, to obtain information on primary care consultations, other consultations, out-ofpocket costs, work-impact of the intervention received and return to work. Unit costs will come from national sources and participating hospitals. The patient questionnaire will also be used to administer the EQ-5D, which will also be obtained at baseline. The main health economic outcome will be within-trial and extrapolated quality adjusted life-years, estimated using the EQ-5D.

Incremental cost-effectiveness will be calculated as the net cost per quality-adjusted life year gained, for arthroscopic surgery versus Rest then Exercise, open surgery versus Rest then Exercise, either surgical versus Rest then Exercise and arthroscopic surgery versus open surgery. Power calculations (see following section) are based on clinical rather than cost-effectiveness outcomes, which will be estimated rather than used in hypothesis testing. Cost-effectiveness ratios and net-benefit statistics will be calculated. We will report within-trial cost-effectiveness; if the trial produces sufficient evidence to plausibly model future quality of life or costs (e.g. based on projected failure rates) we will also extrapolate long-term cost-effectiveness beyond the trial period.

An important component of this trial will be assessment of cost. Therefore, an accurate record of procedures at each of the proposed centres is essential. To evaluate costs of each type of surgery, information from the operating theatres will be collected. Theatre managers will be contacted and visited at each site. Resources used, equipment costs and standard procedures

for rotator cuff repairs will be looked at. Per case information will also be analysed. A checklist of equipment, consumables, implants, time and staff utilized during each case will be completed by theatre staff. Information from theatres will be collected by the Oxford UKUFF office and used in a cost comparison between the arthroscopic and open surgery.

6. SAMPLE SIZE AND FEASIBILITY

6.1 Sample size sought

Based on our experience of using and developing the OSS score in a variety of settings, a 3 point difference (0.33 of a SD) would be deemed a clinically important change. Using the informal survey of surgeons' preferences, we aim to recruit at least 8 surgeons to stratum A, 10 to stratum B and 40 to stratum C. From this we have assumed the following numbers of participants in each strata: Stratum A – 70 participants in each group; stratum B - 120 arthroscopic surgery : 120 Rest then Exercise management and stratum C - 120 open surgery : 120 Rest then Exercise management (see Table 1) giving 690 participants in total.

Table 1 – Proposed number of randomised participants

	Arthroscopic surgery	Open surgery	Rest then Exercise
Stratum A	70	70	70
StratumB	120	None	120
StratumC	None	120	120

For comparison (i), results from the arthroscopic surgery and Rest then Exercise groups in strata A and B can be combined without introducing any systematic bias (resulting in 190 arthroscopic:190 Rest then Exercise). Such a study has greater than 80% power at 2.5% significance level (to account for multiple testing) to detect a difference in mean OSS of 0.33 of a SD, using a two sample two-sided t-test. With an SD of about 9, this would translate to having adequate power to be able to detect a difference in mean OSS score between two groups of about 3 units.

For comparison (ii), the same power (>80%) and detectable difference (0.33 of a SD) as given above are obtained by combining the open surgery and Rest then Exercise management groups in strata A and C (n=190 in each arm).

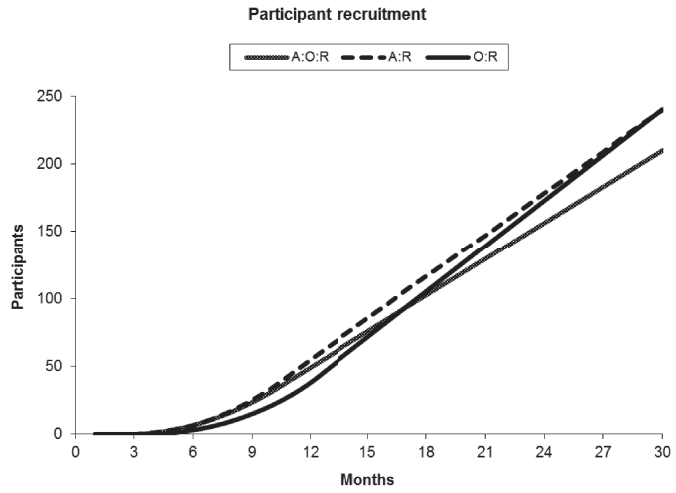
For comparison (iii), due to the small numbers of surgeons willing to randomise to this comparison we propose to use a mixture of direct (randomised) and indirect (non randomised) comparisons. The direct comparison is in stratum A where 70 arthroscopic: 70 open surgeries have 80% power at 2.5% significance to detect a difference of 0.5 of a SD. An indirect comparison using only the results from strata B and C would have 80% power (at 2.5% significance level) to detect a difference of 0.55SD18. Combining the direct and indirect comparison estimate (using recognised meta analysis techniques) gives approximately 80% power at 2.5% significance to detect a difference of 0.38SD.

Attrition is expected to be low (10%) as are the effects of clustering of outcomes within surgeon19,20 (intra cluster correlation less than 0.03). Whilst we do not have a direct estimate from a shoulder trial, other orthopaedic datasets available to our team (e.g. KAT) support this low ICC estimate. Both these factors require the sample size to be inflated; however, the primary analysis adjusts for baseline OSS score which conversely allows the sample size to be decreased by a factor of (1-correlation squared)21. Our previous studies (section 3.2) showed that the correlation in the OSS score pre surgery to 6 months post surgery in patients similar to potential trial participants was 0.57. Assuming a conservative correlation of 0.5 implies that the sample size could be reduced by 25% and still maintains the same power. Therefore, a study with 690 participants will still have sufficient power to detect a clinically
important change in each comparison assuming attrition and clustering accounts for approximately 25% of variation in the data.

6.2 Recruitment rate

Trial centres will be recruited in a staggered way, bringing on 3 centres in each of months 4 and 5, and then 6 or 7 centres per month during months 6 through 13, making a total of 58 centres (8 in menu A:O:R; 10 in menu A:R, and 40 in menu O:R). Steady state will be achieved by month 11 for the two menus involving arthroscopy, and by month 13 for the O:R option. We anticipate having in aggregate 188 centre months for A:O:R (steady state monthly rate of 9 to achieve 210 participants), 233 centre months for A:R (steady state monthly rate 10 to achieve 240 participants, and 856 centre months for O:R (steady state monthly rate 11 to achieve 240 participants), or 690 randomised participants in total. The Hospital Episode Statistics data for 2004/2005 indicates that 1295 rotator cuff repairs took place in NHS hospitals in England alone giving a mean of 15 per trust. With fifty eight centres recruited there is a potential recruitment rate in the order of 75 patients per month. In steady state we will need to be recruiting 30 patients per month, or 40% of the available throughput. Expected recruitment milestones will be 16 (month 6); 142 (month 12); 320 (month 18); 507 (month 24) and 690 (month 30).

Participant recruitment



We anticipate that the trial will require the participation of 58 centres. If the recruitment of patients is failing to meet targets and cannot be increased at participating centres then we would increase the number of centres in the trial.

7. ORGANISATION

7.1 In summary

A detailed plan and timetable of study organisation is given in the Gantt chart (Appendix VI). In summary, it is as follows – 1-4 months: set up office, assemble team, obtain ethical approval and establish first centre; 5-13 months: establish study in all centres; 4-30 months: identify and recruit participants into the study; 12-38 months: 8 month post-randomisation follow-up complete; 16-42 months: 12 month post-randomisation follow-up complete, including one year post-operative MRI scan; 28-54 months: 24 month post-randomisation follow-up complete and database closure; 54-60 months: complete data collection, analysis and dissemination.

7.2 Local organisation in centres

The trial is designed to limit the extra work required by the collaborating clinicians to tasks that only they can do. The research teams in Oxford and Aberdeen will facilitate the trail remotely and initiate site visits as required.

7.2.1 Lead consultant surgeon

Each collaborating centre will identify a lead consultant surgeon who will be the point of contact for that centre. The responsibility of this person will be to:

- establish the study locally (e.g. facilitate local research ethics committee approval, liaise with the local R&D manager and inform all relevant local staff about the study)
- take responsibility for the conduct of the research locally
- notify the study office in Oxford of any unexpected clinical events which might be related to study participation
- provide support and supervision for the local research nurse if applicable
- represent the centre at UKUFF collaborators meetings
- initiating recruitment of participants
- maintaining communication with the study office in Oxford regarding allocated surgical treatment, date of operation, discharge instructions and surgery withdrawal
-

7.2.2 Research nurse (if applicable)

Some centres will identify a research nurse to organise the recruitment of the participants. The responsibility of this person will be to:

- keep regular contact with the lead consultant surgeon and notify them of any problem or unexpected development
- maintain regular contact with the study office
- keep local staff informed of the progress of the study
- assist the lead surgeon to inform the participants about the study and answer any questions they may have
- obtain written consent from the participant
- supply participant with the invitation letter, full consent form (if applicable), baseline questionnaires and a pre-paid envelope for their return to the study office in Oxford
- represent the centre at collaborators meetings

7.3 Central organisation of the study

Reflecting the complex nature of the trial, trial functions will be divided between the Oxford coordinating team and the Aberdeen coordinating team.

7.3.1 Study co-ordination in Oxford

The UKUFF study team in Oxford is divided between the Nuffield Department of Orthopaedic Surgery (NDOS) and the Department of Public Health and Primary Care (DPHPC). Both departments are a part of the University of Oxford with NDOS having very strong links with the Nuffield Orthopaedic Centre NHS Trust.

7.3.1.1 NDOS

The NDOS team will be responsible for all clinical aspects of the trial including; the recruitment and education of surgeons, recruitment of participants, the coordination of the Rest then Exercise Programme, daily management and troubleshooting of clinical issues from staff and participants in the trial and the coordination of the 12 month post operative MRI scans.

7.3.1.2 DPHPC

The UKUFF team in DPHPC are responsible for the design, conduct and analysis of the concurrent economic evaluation and outcome questionnaires.

7.3.1.3 Timing of meetings

All members of the management team in Oxford will aim to meet quarterly to review trial progress. NDOS members will aim to meet weekly to discuss site, surgeon and patient recruitment.

7.3.2 Study co-ordination in Aberdeen

The Aberdeen team are based at the Centre for Health and Randomised Trials within the Health Services Research Unit at the University of Aberdeen. They will be responsible for all data aspects of the trial including: the design and set-up of trial databases, the randomisation system, the management of postal participant follow-up, data management and verification and the conduct of final trial analysis.

7.3.2.1 Timing of meetings

The management team in Aberdeen will meet weekly and a conference call with the CI and trial coordinator in Oxford will occur fortnightly.

7.3.3 Production of reports

The production of all interim reports for the trial steering committee, data monitoring committee, and progress reports required by the funding body, sponsor and ethical committees will be completed in collaboration with all teams and coordinated by the trial managers in Oxford and Aberdeen.

7.4 UKUFF Management Group

The trial management group will oversee all aspects of the conduct and progress of the trial and ensure that the protocol is adhered to. They will be responsible for the daily management

of the trial and will meet at 6 monthly intervals to review the progress of the trial. The group consists of the grant holders and representatives from both the study office in Oxford and Aberdeen.

7.5 UKUFF Steering Committee

The study is overseen by an independent Steering Committee. The chairman is Professor Jeremy Fairbank, with Miss Jo Gibson and Mr Dair Farrar-Hockley acting as the other independent members. The study grant holders, along with Mr David Stanley, complete the Steering Committee. This committee will meet annually or more frequently if circumstances dictate. They will take responsibility for any major decisions, such as the need to close recruitment or more parts of the study or to change the protocol for any reason.

7.6 Data and Safety monitoring

7.6.1 UKUFF DataMonitoring Committee

The Data Monitoring Committee is independent of the study organisers. The chairman is Mr Roger Emery, a Reader in Orthopaedic Surgery, along with Dr Jeremy Lewis (Reader in Physiotherapy) and Dr Richard Morris (Senior Lecturer in Medical Statistics). During the period of recruitment to the study, interim analyses will be supplied, in the strictest confidence, to the data monitoring committee, together with any other analyses that the committee may request. This may include analyses of data from other comparable trials. In light of these interim analyses, the Data Monitoring Committee will advise the Steering Committee if, in its opinion, the trial has provided both:

a) proof beyond reasonable doubt that for all or some types of participants one intervention is clearly indicated in terms of clinical and cost effectiveness
b) evidence that might reasonably be expected to influence materially the care of the people with rotator cuff tears by clinicians who know the results of this and comparable trials.

The Steering Committee can then decide whether or not to modify intake to the trial. Unless this happens, the Steering Group, Management Group, consultant surgeons and study office staff (except those you supplied the confidential analyses) will remain ignorant of the interim results.

The frequency of the interim analyses will depend on the judgement of the Chairman of the committee, in consultation with the Steering Committee.

7.6.2 Safety concerns

The UKUFF trial involves three interventions that are well established in clinical practise, although unproven for clinical and cost effectiveness. Two of these interventions are surgical and so inevitably there are safety concerns surrounding them. These include:

- surgical site infection
- frozen shoulder
- complications relating to anaesthetic and or theatre equipment
- uncontrolled bleeding

As the techniques are standard treatments for rotator cuff tears, and because the surgeons are performing their usual and preferred surgical procedures, the trial participants would not be

put at any more risk than is normally associated with the treatment. It is anticipated that none of these events would be classified as a serious adverse event but we would respond appropriately to any notification (Appendix VII).

Collaborators and participants may contact the chairman of the Steering Committee through the trial office in Aberdeen or Oxford about any concerns they may have about the trial. If concerns arise about procedures, participants or clinical or research staff (including risk to staff) these will be relayed to the Chairman of the Data Monitoring Committee.

7.6.3 Data handling and record keeping

All data collected and stored as a result of the study will comply with the data protection act.

8. FINANCE

The UKUFF trial is funded by the UK NHS Health Technology Assessment Programme (Ref: 05/47/02). The Nuffield Department of Orthopaedic Surgery in Oxford will manage the finances and budget.

Participating sites will be asked to invoice the UKUFF study quarterly in order to receive the payment of £200 per randomised patient. The trial coordinator will supply each site with their recruitment numbers at the end of each quarter so the invoice can be raised for the correct amount.

Participating sites will also be asked to invoice the UKUFF study quarterly in order to receive the payment for the required MRI scan. The cost of these scans will be negotiated with each site before the first scan is undertaken. This cost is entered into the Clinical Trial Agreement implemented between the site and the University of Oxford.

9. SATELLITE STUDIES

The funds provided by the HTA Programme are to conduct the main trial as described in this protocol. Nevertheless, it is recognised that the value of the UKUFF trial will be enhanced by smaller ancillary studies of specific aspects. Plans for such studies should, however, be discussed and agreed in advance with the Management Group. Details of all satellite studies are outlined in Appendix VIII.

10. INDEMNITY

The UKUFF study is sponsored by the University of Oxford. Indemnity and/or compensation for negligent harm arising specifically from an accidental injury for which the University is legally liable as the Research Sponsor will be covered by the University of Oxford.

The University of Oxford have authority to audit the process of the UKUFF trial. Authorised University staff may review aspects of the trial, such as; the consenting process, data collection and storage. UKUFF state that a period of 10 working days notice must be given before these reviews occur.

The NHS will owe a duty of care to those undergoing clinical treatment, with Trust Indemnity available through the NHS Litigation Authority Scheme.

11. PUBLICATION

The success of the trial depends entirely on the wholehearted collaboration of a large number of health care workers. For this reason, chief credit for the trial will be given, not to the committees or central organisers, but to all those who have wholeheartedly collaborated in the trial. The trials' publication policy is described in Appendix IX. The results of the trial will be reported first to trial collaborators. The main report will be drafted by the UKUFF Management Group, and the final version will be agreed by the Trial Steering Committee before submission for publication, on behalf of the UKUFF collaborators.

To safeguard the integrity of the main trial, reports of satellite studies will not be submitted for publication without prior agreement from the UKUFF Management Group.

We plan to maintain interest in the study by publication of UKUFF newsletters at three monthly intervals for collaborators and annually for participants. The newsletters will inform their audience of how the study and recruitment is progressing and any relevant interim results. UKUFF have deemed it important to communicate with the collaborators so that common problems may be addressed and protocol adherence may be monitored.

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