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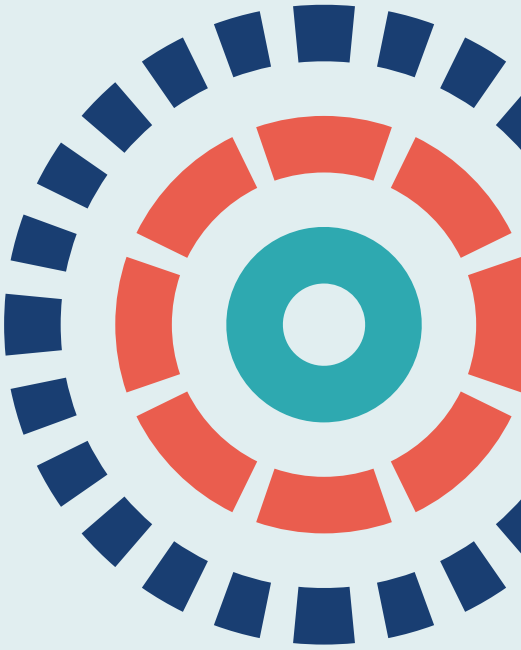

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Arthroscopic hip surgery compared with personalised hip therapy in people over 16 years old with femoroacetabular impingement syndrome: UK FASHIoN RCT

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Declared competing interests of authors: Damian R Griffin is a surgeon with a hip preservation practice that includes treating femoroacetabular impingement syndrome and hip arthroscopy, and he reports consulting and teaching fees from Stryker UK (Newbury, UK) and Smith & Nephew UK (Watford, UK), outside the submitted work. Joanna Smith is a physiotherapist who treats patients with femoroacetabular impingement syndrome. Peter DH Wall is a hip surgeon who treats patients with femoroacetabular impingement syndrome. Nadine Foster is a member of Clinical Trial Units that were funded by the National Institute for Health Research until 2021 and was a member of the Health Technology Assessment Primary Care, Community and Preventive Interventions Panel (2010–15). Jenny Donovan reports membership of the Rapid Trials and Add-on Studies Board (2012 to present) and the Health Technology Assessment Commissioning Committee (2006–12).

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This report

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Abstract

Arthroscopic hip surgery compared with personalised hip therapy in people over 16 years old with femoroacetabular impingement syndrome: UK FASHIoN RCT

Damian R Griffin,[1,2*] Edward J Dickenson,[1,2] Felix Achana,[1] James Griffin,[1] Joanna Smith,[2] Peter DH Wall,[1,2] Alba Realpe,[1] Nick Parsons,[1] Rachel Hobson,[1] Jeremy Fry,[3] Marcus Jepson,[4] Stavros Petrou,[1] Charles Hutchinson,[1,2] Nadine Foster[5] and Jenny Donovan[4]

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Background: Femoroacetabular impingement syndrome is an important cause of hip pain in young adults. It can be treated by arthroscopic hip surgery or with physiotherapist-led conservative care.

Objective: To compare the clinical effectiveness and cost-effectiveness of hip arthroscopy with best conservative care.

Design: The UK FASHIoN (full trial of arthroscopic surgery for hip impingement compared with non-operative care) trial was a pragmatic, multicentre, randomised controlled trial that was carried out at 23 NHS hospitals.

Participants: Participants were included if they had femoroacetabular impingement, were aged ≥ 16 years old, had hip pain with radiographic features of cam or pincer morphology (but no osteoarthritis) and were believed to be likely to benefit from hip arthroscopy.

Intervention: Participants were randomly allocated (1 : 1) to receive hip arthroscopy followed by postoperative physiotherapy, or personalised hip therapy (i.e. an individualised physiotherapist-led programme of conservative care). Randomisation was stratified by impingement type and recruiting centre using a central telephone randomisation service. Outcome assessment and analysis were masked.

Main outcome measure: The primary outcome was hip-related quality of life, measured by the patient-reported International Hip Outcome Tool (iHOT-33) 12 months after randomisation, and analysed by intention to treat.

Results: Between July 2012 and July 2016, 648 eligible patients were identified and 348 participants were recruited. In total, 171 participants were allocated to receive hip arthroscopy and 177 participants were allocated to receive personalised hip therapy. Three further patients were excluded from the trial after randomisation because they did not meet the eligibility criteria. Follow-up at the primary outcome assessment was 92% ($N = 319$; hip arthroscopy, $n = 157$; personalised hip therapy, $n = 162$). At 12 months,

mean International Hip Outcome Tool (iHOT-33) score had improved from 39.2 (standard deviation 20.9) points to 58.8 (standard deviation 27.2) points for participants in the hip arthroscopy group, and from 35.6 (standard deviation 18.2) points to 49.7 (standard deviation 25.5) points for participants in personalised hip therapy group. In the primary analysis, the mean difference in International Hip Outcome Tool scores, adjusted for impingement type, sex, baseline International Hip Outcome Tool score and centre, was 6.8 (95% confidence interval 1.7 to 12.0) points in favour of hip arthroscopy ($p = 0.0093$). This estimate of treatment effect exceeded the minimum clinically important difference (6.1 points). Five (83%) of six serious adverse events in the hip arthroscopy group were related to treatment and one serious adverse event in the personalised hip therapy group was not. Thirty-eight (24%) personalised hip therapy patients chose to have hip arthroscopy between 1 and 3 years after randomisation. Nineteen (12%) hip arthroscopy patients had a revision arthroscopy. Eleven (7%) personalised hip therapy patients and three (2%) hip arthroscopy patients had a hip replacement within 3 years.

Limitations: Study participants and treating clinicians were not blinded to the intervention arm. Delays were encountered in participants accessing treatment, particularly surgery. Follow-up lasted for 3 years.

Conclusion: Hip arthroscopy and personalised hip therapy both improved hip-related quality of life for patients with femoroacetabular impingement syndrome. Hip arthroscopy led to a greater improvement in quality of life than personalised hip therapy, and this difference was clinically significant at 12 months. This study does not demonstrate cost-effectiveness of hip arthroscopy compared with personalised hip therapy within the first 12 months. Further follow-up will reveal whether or not the clinical benefits of hip arthroscopy are maintained and whether or not it is cost-effective in the long term.

Trial registration: Current Controlled Trials ISRCTN64081839.

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List of abbreviations

AE	adverse event
BNF	*British National Formulary*
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	case report form
CSP	Chartered Society of Physiotherapy
DMC	Data Monitoring Committee
EQ-5D	EuroQol-5 Dimensions
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
FAI	femoroacetabular impingement
GP	general practitioner
HRG	Healthcare Resource Group
ICER	incremental cost-effectiveness ratio
iHOT-33	International Hip Outcome Tool-33
IQR	interquartile range
MAHORN	Multicenter Arthroscopy of the Hip Outcomes Research Network
MCID	minimum clinically important difference
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
PHT	personalised hip therapy
PI	principal investigator
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
QRI	qualitative recruitment intervention
R&D	research and development
RA	research associate
RCT	randomised controlled trial
SAE	serious adverse event
SD	standard deviation
SE	standard error
SF-6D	Short Form questionnaire-6 Dimensions
SF-12	Short Form questionnaire-12 items
SOP	standard operating procedure
TMG	Trial Management Group
TSC	Trial Steering Committee
VAS	visual analogue scale
WCTU	Warwick Clinical Trials Unit

Plain English summary

In some people, the ball and the socket of the hip joint develop so that they do not fit together properly. This is called hip impingement, and is an important cause of hip and groin pain in young and middle-aged adults. Treatments include physiotherapy and surgery. Physiotherapy typically involves a programme of 6–10 outpatient consultations that aim to strengthen the muscles around the hip: we called this personalised hip therapy. Surgery can be carried out by a keyhole operation, called a hip arthroscopy, which aims to reshape the hip to prevent impingement. Surgery is normally followed by some physiotherapy. We performed a research study to compare the results of hip arthroscopy and personalised hip therapy in people with hip impingement.

A total of 348 people with painful hip impingement in 23 hospitals in the UK agreed to take part. About half were treated with hip arthroscopy and half with personalised hip therapy. We used questionnaires to ask participants about pain in the hip and their ability to do everyday things at 6 months and 1 year after entering the study. At 2 and 3 years, we asked if patients required any additional treatments.

We found that both groups improved, but those treated with hip arthroscopy improved a moderate amount more than those treated with personalised hip therapy. However, these improvements were not cost-effective compared with personalised hip therapy at 1 year.

We need to see whether or not this difference continues after several years, but the results, so far, suggest that if a person has painful hip impingement, then hip arthroscopy offers greater improvements than personalised hip therapy.

Scientific summary

Background

Femoroacetabular impingement (FAI) syndrome is a painful disorder of the hip. FAI syndrome is caused by a premature contact between the femur and acetabulum during hip movements. This premature contact typically occurs as a result of certain hip shapes, for example cam or pincer morphology. Cam morphology refers to a flattening or convexity at the femoral head–neck junction, whereas pincer morphology refers to a focal or global overcoverage of the femoral head by the acetabulum. FAI syndrome leads to progressive damage within the joint, including the acetabular labrum and articular cartilage, and is associated with the development of osteoarthritis of the hip.

Surgery has become an established treatment for FAI syndrome and hip arthroscopy, in particular, is widespread. The aim of surgery is to reshape the hip joint to prevent impingement. Intra-articular injury, such as a cartilage and labral damage, can be resected, repaired or reconstructed. Non-operative treatments for FAI syndrome include exercise-based packages of conservative care delivered by a physiotherapist.

Many case series report improvement in patients with FAI syndrome after open or arthroscopic surgery, or physiotherapy. However, a 2014 Cochrane review of surgery for treating FAI syndrome showed that there was no randomised controlled trial (RCT) evidence to support these treatments [Wall PD, Brown JS, Parsons N, Buchbinder R, Costa ML, Griffin D. Surgery for treating hip impingement (femoroacetabular impingement). *Cochrane Database Syst Rev* 2014;**9**:CD010796].

Our aim was to assess the effectiveness of hip arthroscopy in treating patients with FAI syndrome. In a feasibility study, we established that patients were prepared to be recruited, and that surgeons were in equipoise and willing to recruit patients to a trial that compared hip arthroscopy with best conservative care. In this pragmatic, multicentre RCT, we assessed the clinical effectiveness and cost-effectiveness of hip arthroscopy compared with best conservative care in patients with FAI syndrome.

Methods

We conducted a pragmatic, multicentre, two-arm, assessor-blind RCT. An initial feasibility study was treated as an internal pilot so that participants who took part were included in the main trial recruitment. The study was performed in 23 NHS hospitals in the UK.

Participants were recruited from the specialist hip arthroscopy services at 23 NHS hospitals. Participating surgeons identified eligible patients during routine diagnostic consultations. Assessments included history, clinical examination, plain radiographs and cross-sectional imaging [i.e. magnetic resonance imaging (MRI) or computerised tomography, or both]. The surgeon classified patients as having cam impingement (defined as an alpha angle of $> 55°$), pincer impingement (defined as a lateral centre-edge angle of $> 40°$ or a positive crossover sign) or mixed-type impingement (i.e. a combination of both).

Qualitative research to understand recruitment as it occurred was integrated into the trial. Findings were used to design a recruiter training and centre support programme that was implemented to optimise recruitment.

Inclusion and exclusion criteria

Patients were eligible to participate if they had hip pain, had radiographic features of cam or pincer morphology, were aged ≥ 16 years old and were able to give informed consent, and if the treating surgeon believed that they were likely to benefit from hip arthroscopy. Patients were excluded if they had hip osteoarthritis (i.e. Tönnis grade > 1 or loss of > 2 mm of superior joint space on an anteroposterior radiograph), a history of hip pathology (such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis) or of previous hip injury (such as acetabular fracture, hip dislocation or femoral neck fracture) or if they had already had undergone shape-changing surgery (open or arthroscopic) of the hip. Patients with bilateral FAI syndrome were eligible and the most symptomatic hip was randomised and followed. Trained research associates (RAs) approached eligible patients to explain the trial and to invite them to participate. All participants gave written informed consent.

Interventions

Surgical intervention

Hip arthroscopy was performed by a senior surgeon who was trained and experienced in hip arthroscopy. Trial surgeons reported that they performed a mean of 12 [standard deviation (SD) 55] hip arthroscopies per year during the study. Shape abnormalities and consequent labral and cartilage pathology were treated. Adequacy of bony reshaping was assessed by intraoperative image intensifier views or by arthroscopic visualisation of a satisfactory impingement free range of movement of the hip, or both. Patients were referred to outpatient physiotherapy services for a course of rehabilitation, as per usual care for that surgeon. These postoperative physiotherapists were distinct from those providing conservative care to avoid contamination between groups. Patients had a scan of their hip at least 6 weeks after surgery. A panel of international experts assessed the fidelity of the surgery. They reviewed operation notes, intraoperative images and postoperative scans to subjectively assess whether or not adequate surgery, according to the protocol, had been undertaken.

Best conservative care

Personalised hip therapy (PHT) is a package of physiotherapist-led rehabilitation for FAI syndrome. Although the name for this intervention is new, the care offered was based on a consensus of what physiotherapists, physicians and surgeons regarded as best conservative care for FAI syndrome. Care was delivered by at least one physiotherapist at each centre who was trained formally in this protocol via a 1-day workshop and supported to deliver PHT through refresher workshops. At their initial assessment, participants received a PHT information pack that described what to expect during the course of their treatment. Participants then had between 6 and 10 contacts with the physiotherapist over 12–24 weeks. Some of the contacts were conducted by either telephone or e-mail if geographical distance prevented all contacts being carried out face to face. Exercise diaries were available for physiotherapists to monitor compliance. Physiotherapists recorded full details of their advice and treatments, number and type of treatment contacts, and any non-attendance on case report forms (CRFs). These CRFs were reviewed for accuracy in comparison to the usual physiotherapy records at each treatment centre and then assessed for fidelity to the protocol by a panel comprising members of the core group who developed the protocol for PHT.

Outcomes

The primary outcome was hip-related quality of life measured by the International Hip Outcome Tool-33 (iHOT-33) at 12 months after randomisation. The instrument has been validated in a relevant population for this trial and has a minimum clinically important difference (MCID) of 6.1 points. Secondary outcomes were health-related quality of life measured using the EuroQol-5 Dimensions,

five-level version (EQ-5D-5L) and the Short Form questionnaire-12 items (SF-12) v2, adverse events and resource use. Patients reported complications 6 weeks following the start of their intervention. iHOT-33, EQ-5D-5L, SF-12, complications and health-care resource use were collected by questionnaires that were administered centrally. Scores for these measures were collected at the time of consent and again by postal questionnaire at 6 and 12 months after randomisation. Information on further procedures was collected at 2 and 3 years post randomisation.

Randomisation

Participants were randomised (1 : 1) to receive either hip arthroscopy or best conservative care using a minimisation algorithm for centre and type of impingement. All baseline data were collected prior to randomisation, which was performed by the recruiting RA. Allocation concealment was ensured by using a secure telephone randomisation service. It was not possible to blind patients or the treating clinicians to their allocation. Researchers who collected outcome assessments and analysed the results were blind to allocation.

Analyses

The planned sample size was 172 participants in each group, based on a SD iHOT-33 score of 16 points and a MCID of 6.1 points, giving a standardised effect size of 0.38. We designed the trial to have 90% power to detect an effect of this size at a two-sided 5% significance level, allowing for up to 15% loss to follow-up at the primary outcome time point.

The primary analysis investigated differences in the primary outcome measure (i.e. iHOT-33 score) between the two treatment groups at 12 months after randomisation on an intention-to-treat basis. We assessed the primary outcome 12 months from randomisation rather than from intervention because this was a pragmatic trial design of two different treatment strategies. A mixed-effects regression analysis was used to assess the effects of the interventions on 12-month iHOT-33 scores, after adjusting for the fixed effects of impingement type, sex and baseline iHOT-33 score, with recruiting centre included as a random effect to model any potential associations within the recruiting centres. No interim analyses were planned.

Our primary inferences were drawn from an intention-to-treat analysis, irrespective of compliance and without imputation for missing data. Prespecified subgroup analyses were performed for different impingement types (i.e. cam, pincer and mixed) and for patients aged < 40 years and > 40 years.

An economic evaluation was conducted from a UK NHS and Personal Social Services perspective. Economic costs associated with the delivery of the two interventions were estimated. Resource use questions completed by participants at each assessment point provided a profile of all hospital inpatient and outpatient service use, community health and social care encounters, prescribed medications and NHS supplies, such as crutches and home adaptations.

Results

A total of 648 patients attending the participating surgeons' hip clinics between 20 July 2012 and 15 July 2016, were deemed eligible of whom 351 (54%) agreed to participate. Three participants were randomised but subsequently found not to meet the eligibility criteria and, therefore, were excluded from further analysis. In total, 171 participants were allocated to hip arthroscopy and 177 to PHT.

Participants in the two groups were well matched in terms of both demographics and pre-randomisation hip-related quality of life, having had symptoms for approximately 3 years. Fourteen (8%) participants who were allocated to PHT had all or part of this intervention, but then, at their request, went on to have hip arthroscopy within 12 months after randomisation. No patients allocated to hip arthroscopy had PHT. The median time from randomisation to treatment was 122 [interquartile range (IQR) 80–185] days for hip arthroscopy and 37 (IQR 22–60) days for PHT. Twenty-seven (16%) participants allocated hip arthroscopy did not receive it by the 12-month time point. Of those participants who did receive hip arthroscopy, 84% (121/144) had postoperative MRI and their case was assessed by the surgical review panel. Among these participants, surgery was deemed to have been performed with high fidelity for 87% (105/12) and to be unsatisfactory for 13% (16/121). The most common reason for unsatisfactory surgery was an inadequate bony resection ($n = 7$) and a sharp transition from the femoral head to neck ($n = 5$) as a result of reshaping surgery. Five per cent (9/177) of participants allocated to PHT did not receive any treatment by 12 months. Of those participants who received PHT, 69% (107/154) were judged to have received the intervention to a high fidelity. The most common reason for lack of PHT fidelity was participants not receiving the minimum of six PHT sessions (34/46, 74%).

A total of 319 (92%) participants completed questionnaires at 12 months after randomisation; seven participants withdrew from follow-up and 22 participants were lost to follow-up. The iHOT-33 score increased between baseline and 6 months and between 6 and 12 months, indicating an improvement in hip-related quality of life. In the primary intention-to-treat analysis at 12 months, the adjusted estimate of treatment effect measured with the iHOT-33 was 6.8 [95% confidence interval (CI) 1.7 to 12.0; $p = 0.009$] in favour of hip arthroscopy compared with PHT.

In the as-treated (per-protocol) analysis at 12 months, including participants who received PHT ($n = 154$) or hip arthroscopy ($n = 144$), the adjusted estimate of the between-group difference on the iHOT-33 was 8.2 (95% CI 2.8 to 13.6) points in favour of hip arthroscopy. In the exploratory secondary analysis based on those participants whose treatment was deemed to have been of high fidelity (hip arthroscopy, $n = 105$; PHT, $n = 107$), the adjusted estimate of between-group difference on the iHOT-33 was 5.8 (95% CI −0.7 to 12.2) points in favour of hip arthroscopy.

In the prespecified subgroup analysis, the between-group difference on the iHOT-33 was 5.0 (95% CI −1.2 to 11.3) points in participants aged < 40 years and 10.9 (95% CI 1.7 to 20.1) points in participants aged > 40 years. In addition, in the prespecified subgroup analysis, the between-group difference on the iHOT-33 was 8.3 (95% CI 2.5 to 14.2) points in participants with cam morphology, 1.1 (95% CI −11.5 to 13.7) points in participants with mixed cam and pincer morphology and 4.0 (95% CI −14.6 to 22.7) points in participants with pincer morphology, in favour of hip arthroscopy. There were no statistically significant between-group differences in SF-12 or EQ-5D-5L scores at 6 or 12 months post randomisation.

At 6 weeks post intervention, the most frequently reported complication was muscle soreness. At 12 months, seven serious adverse events had been reported. Six of these serious adverse events were among the participants in the hip arthroscopy group (one failed discharge from the day surgery unit and required an overnight admission, one scrotal haematoma necessitated the patient's readmission, two superficial wound infections required treatment with oral antibiotics, one deep wound infection led to further surgery and ultimately a total hip replacement, and one participant had a fall that was unrelated to the hip arthroscopy). One participant in the PHT group developed biliary sepsis that was unrelated to PHT.

The level of missing item-level data was low (iHOT-33 0.6%) for all patient-reported outcome measures at all time points. After imputation for missing data, the adjusted estimate of treatment effect was almost unchanged at 6.6 (95% CI 1.7 to 11.4) points in favour of hip arthroscopy. There was no difference in iHOT-33 scores at 12 months for hip arthroscopy patients treated within 6 months of randomisation or later (0.9, 95% CI −10.7 to 8.8). The mean cost of hip arthroscopy was £3042 (35% staff time, 28% surgical devices and anaesthetic drugs, 19% theatre running costs and 18%

bed-day costs). Participants in the PHT group attended a mean of six physiotherapy sessions (average duration of 30 minutes), generating a mean total treatment cost of £155 per participant. The adjusted incremental cost of hip arthroscopy compared with PHT during the 12-month follow-up was £2483, with incremental quality-adjusted life-years (QALYs) of –0.018 (representing a net QALY loss).

Conclusion

We have shown that offering hip arthroscopy to patients with FAI syndrome leads to better clinical outcomes at 12 months than best conservative care. However, this improvement comes at a cost. Our study does not demonstrate cost-effectiveness of hip arthroscopy compared with conservative care within the first 12 months, and further follow-up is required (5 and 10 years are planned) to establish clinical effectiveness and cost-effectiveness in the longer term. Future work should include characterisation of those patients who gain most from surgery compared to best conservative care. A qualitative recruitment intervention was able to maximise recruitment of eligible participants by improving research nurse and clinicians communication with patients.

Trial registration

This trial is registered as ISRCTN64081839.

Funding

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Chapter 1 Introduction

Further reading on this trial is available in the trial protocol by Griffin *et al.*,[1] trial feasibility reports by Griffin *et al.*[2,3] and Wall,[4] trial non-operative intervention report by Wall *et al.*[5] and trial results article by Griffin *et al.*[6]

Background

Until recently, there was little understanding of the causes of hip pain in young adults. A proportion of young adults with hip pain have established osteoarthritis, inflammatory arthritis, avascular necrosis, fractures or childhood hip disease, but the majority have no specific diagnosis. Over the last decade, there has been increasing recognition of femoroacetabular impingement (FAI) syndrome, which seems to account for a large proportion of the previously undiagnosed cases of hip pain in young adults.[7,8] Subtle deformities in the shape of the hip (ball and socket joint) combine to cause impingement between the femoral head (ball) or neck and the anterior rim of the acetabulum (socket), most often in flexion and internal rotation.[7,9] Excess contact force leads to damage to the acetabular labrum (fibrocartilage rim of the socket) and the adjacent acetabular cartilage surface.[7] FAI seems to be associated with progressive articular degeneration of the acetabulum and may account for a significant proportion of so-called idiopathic osteoarthritis, although this remains unproven.[9] The shape abnormalities of the hip joint are typically divided into the following three categories:[9]

1. cam-type impingement (in which the femoral head is oval rather than round, or there is prominent bone on the femoral neck)
2. pincer-type impingement (in which the rim of the acetabulum is too prominent in one or more areas of its circumference)
3. mixed-type hip impingement (which is a combination of cam and pincer types).

Surgery can be performed to improve bone shapes to prevent impingement between the femoral neck and rim of the acetabulum. In the case of cam-type FAI syndrome, this usually involves the removal of bone at the femoral head–neck junction. In the case of pincer-type FAI syndrome, it may involve the removal of bone at the rim of the acetabulum. At the same time as bony shape improvement, any soft tissue damage to the cartilage or labrum as a result of the FAI syndrome is debrided, repaired or reconstructed. Surgery can be undertaken using either keyhole (arthroscopic) surgery or more traditional open surgery to access the hip joint and correct the hip shape abnormalities associated with FAI syndrome.

Surgery for FAI syndrome has evolved more quickly than our understanding of the epidemiology or natural history of the condition, and is becoming an established treatment.[10–12] The risks of complications from open surgery are greater than those for arthroscopic surgery, and current evidence suggests that the outcomes of arthroscopic treatment for the symptoms of FAI syndrome are comparable to open surgery.[13,14] Consequently, hip arthroscopy for FAI syndrome is a rapidly growing new cost pressure for health providers.[15] However, a Cochrane review highlighted the absence of randomised controlled trials (RCTs) comparing FAI surgery with conservative care, such as physiotherapist-led exercise.[16]

Multicentre RCTs are acknowledged to be the best design for evaluating the effectiveness of health-care interventions, as they provide robust evidence.[17,18] However, there are often major challenges in performing RCTs of surgical technologies[19] and there were concerns that a RCT of hip arthroscopy in FAI syndrome might not be feasible.

Summary of a feasibility and pilot trial

A feasibility and pilot study commissioned by the Health Technology Assessment programme (reference 10/41/02) was completed.[2,3] It comprised (1) a pre-pilot phase, including patient and clinician surveys and interviews, and a systematic review of non-operative care; (2) a workload survey of hip arthroscopy for FAI; (3) development of best conventional care and arthroscopic surgery protocols; (4) a pilot RCT to measure recruitment rate; and (5) an integrated programme of qualitative research to understand and optimise recruitment.[2,3]

The feasibility study followed the commissioning brief and specifically addressed the following parameters to inform the design of the proposed full-scale RCT.

Define eligibility criteria

The eligibility criteria were initially designed in collaboration with the Multicenter Arthroscopy of the Hip Outcomes Research Network (MAHORN), which is an academic group of highly experienced hip arthroscopists within the International Society for Hip Arthroscopy (Moffat, UK) (URL: www.isha.net). These criteria were then discussed with a further sample of 14 UK specialist hip surgeons with experience of treating patients with FAI syndrome. In individual interviews, a variety of clinical scenarios were presented and the surgeons were asked to describe decision-making for treatment. Minor modifications were made to the eligibility criteria. These criteria were then tested during the recruitment of real patients during the pilot RCT and were found to be easy to apply, with little disagreement among clinicians.

Define a protocol for hip arthroscopy for FAI syndrome

A draft protocol for arthroscopic treatment of FAI was developed in a consensus conference with MAHORN members. This draft was circulated among the sample of 14 UK hip surgeons for feedback. After editing, it was recirculated and approved by all. The protocol was then tested in 21 participants randomised to surgery in the pilot trial. We also developed a method to measure fidelity by intraoperative photographs and postoperative magnetic resonance imaging (MRI), which was assessed by a panel of independent international experts. We showed that this approach was acceptable to surgeons and demonstrated complete adherence to protocol in six of seven operations at the first panel conference.

Define a protocol for best conservative care (comparator)

We performed a systematic review of non-operative care for FAI.[20] This revealed little evidence of a standard for best conservative care, even though many NHS commissioners describe the failure of conservative care as a prerequisite for surgery.[21] There was some evidence that physiotherapy-led non-operative care is most frequently used.[20] This is complemented by established theory and evidence supporting treatment effects for physiotherapy in other painful musculoskeletal conditions, including osteoarthritis and back pain.[22,23]

We used a combination of consensus methods (e.g. Delphi and nominal group techniques) among physiotherapists to agree a protocol for 'best conservative care'.[5] We advertised to relevant networks of the Chartered Society of Physiotherapy (CSP) (London, UK) through their interactive communication system (interactiveCSP) and in the *Frontline* magazine[24] (a twice-monthly magazine posted to 52,000 CSP members in the UK). These advertisements invited physiotherapists to help develop a consensus for a best conservative care treatment protocol for FAI syndrome. Electronic invitations were also sent to physiotherapists in the USA and Australia who were known to us through previous collaborative work on FAI syndrome. To encourage a process of 'snowball sampling' within the international community, these therapists were encouraged to invite colleagues with experience and interest in managing FAI syndrome to join in the consensus process.

We developed a physiotherapy-led four-component protocol to be delivered over 12 weeks, with a minimum of six one-to-one treatment sessions.[5] The protocol included (1) a detailed patient assessment;

(2) education and advice about FAI syndrome; (3) help with pain relief, including hip joint steroid injections if required; and (4) an exercise programme that has the key features of individualisation, supervision and progression. We used a patient focus group to choose the most acceptable name for this protocol of best conservative care. The group made it clear that we should express that this was a coherent and valid alternative to surgery and different from the physiotherapy likely to have been received already, and recommended the name personalised hip therapy (PHT).

In the development of PHT, we struck a balance between the need for a meaningful comparator for hip arthroscopy, the need to ensure that PHT is different from previous physiotherapy that FAI syndrome patients' may have experienced and the need for PHT to be deliverable in the NHS outside a trial. UK physiotherapists and patients felt that PHT was 'best' in that not all patients currently receive such a comprehensive package, but 'conventional' in that all its elements are widely used and the package is deliverable within usual constraints in the NHS. We tested the protocol and a logbook approach to assessing fidelity in 21 participants randomised to PHT in the pilot trial. The protocol was acceptable to patients and physiotherapists, and we demonstrated complete adherence in seven of the first eight participants.

Define willingness of centres and patients to be recruited to a randomised controlled trial

We performed a survey of all orthopaedic surgery departments in NHS hospital trusts in the UK. Clinical directors of those departments reported that 120 consultant surgeons were treating FAI syndrome. We contacted all 120 surgeons who reported having performed 2399 operations for FAI in 2011/12. A total of 1908 operations were performed by hip arthroscopy and 491 operations were open surgery.[3] Thirty-four hospital trusts had a workload of 20 or more hip arthroscopies for FAI syndrome in 1 year. We interviewed 18 of the highest-volume surgeons to explore their views about a trial comparing hip arthroscopy with best conservative care in patients with FAI syndrome. One surgeon felt that he could not participate in a trial because he was certain that surgery worked, five surgeons had a bias towards surgery but recognised the need for a trial and were prepared to randomise patients, and 12 surgeons expressed equipoise and were keen to take part in a trial.

We purposively sampled 18 patients who had been treated for FAI syndrome. Fourteen of these patients had received arthroscopic surgery and five had received physical therapy and steroid injections (one patient had both). These patients had a semistructured interview with a qualitative researcher who had not been involved in their care to explore their experiences of diagnosis and treatment, and their views on the proposed trial. The majority of the patients were young and physically active. Symptoms of FAI syndrome had affected their work, recreation and day-to-day activities, and many reported a great sense of relief when a diagnosis was made. Patients said that both surgical and conservative care would be acceptable. The majority of patients saw surgery as the solution for a condition that they perceived as mainly caused by abnormal bone shapes. On the other hand, non-operative care was perceived as attractive if it might be successful and could avoid the risks of surgery. Some patients commented that they had not been offered a non-operative option and saw this as a positive addition to available treatments. Patients were enthusiastic about research in this field, and about being involved, but had reservations about some of the language involved, for instance 'trial', 'random' and '50 : 50 chance' implied a lack of personalised care. All of these patients said that they would have been prepared to take part in a RCT as long as the treatment options and uncertainty around them had been fully explained, the treatment they received had been personalised for them and they were assured that their care would be continued whatever happened in the research.

Our findings in these in-depth interviews were broadly consistent with Palmer *et al.*'s[25] questionnaire survey of 30 surgeons who performed FAI surgery and 31 patients with a diagnosis of FAI syndrome. In Palmer *et al.*'s[25] study, 71% of surgeons and 90% of patients felt that a trial of this question was appropriate.

We concluded that surgeons in most centres in the UK that perform hip arthroscopy for FAI syndrome, and their patients, would be willing to be included in a RCT.

Understand and optimise recruitment

An important objective of the pilot trial was to explore likely issues in recruitment and to develop optimum procedures for the full trial.

We interviewed all principal investigators (PIs) and research associates (RAs) during the pilot trial to ensure that the study was being described and recruitment procedures were being followed in accordance with the study protocol, and to identify when they were not. We developed training packages to correct common problems. We identified structural features associated with successful recruitment, such as running targeted clinics, having a dedicated RA in attendance and ensuring that referred patients arrived with expectations of receiving treatment for FAI syndrome, rather than being told they had been referred for surgery. This learning was shared across all sites.

We recorded and analysed 87 diagnostic and recruitment consultations with 60 new patients during the pilot trial. We identified where improvements could be made in presenting trial information and in engaging patients to consider participation, guided by our previous work.[26,27] The analysis was targeted at the recruitment levels at specific sites, with individual confidential feedback for recruiters on good practice and areas for improvement, and with anonymised findings being fed back to all sites.

Common difficulties with recruitment that were identified included poorly balanced presentations of treatment options (where surgery was presented at greater length and more favourably than PHT), graphic descriptions of surgery that may have put patients off that option or discouraged participation, presenting trial information in an order that was confusing for patients and surgeons going beyond their protocol brief to explain the trial, rather than referring patients to the trial recruiter for this information. Analysis of the consultations led to the development of a six-step model for the presentation of trial information to optimise recruitment.[3,28]

Estimate recruitment rate

Ten clinical centres participated in the pilot trial and nine opened to recruitment within 6 months. At one site, local research and development (R&D) approval was delayed until just before the end of the pilot and so no one was recruited.

Of the 144 potentially eligible patients with hip problems identified at the pre-clinic screening of referral letters, 60 met the inclusion criteria after assessment and were approached for randomisation. The most frequent reasons for exclusion were a diagnosis other than FAI (53/84) and a judgement that the patient would not benefit from arthroscopic surgery (21/84). Forty-two patients (70% of those eligible) consented to take part in the pilot RCT. Among those who declined ($n = 18$), the most common reasons were a preference for surgery ($n = 11$) and a preference not to have surgery ($n = 3$). The mean duration and recruitment rate across all sites was 4.5 months and one patient per centre per month, respectively. The lead site recruited for the longest period (9.3 months) and recruited the largest number of patients (2.1 patients per month).

Selection of appropriate outcome measures

A variety of outcome measures have been used to study patients with FAI syndrome. Some, such as the Western Ontario and McMaster Universities Arthritis Index (WOMAC®) and the Harris Hip Score, were intended for older patients with symptoms of severe arthritis and are most suitable to measure the effect of hip replacement surgery.[29,30] These measures tend to exhibit ceiling effects and are not sensitive to change after treatment in patients with FAI syndrome.[30,31]

The Non-Arthritic Hip Score is a self-administered instrument to measure hip-related pain and function in younger patients without arthritis. The score is valid compared with other measures of hip

performance, is internally consistent and is reproducible.[32] However, it is not patient derived, raising concern that it may not measure what is most important to patients.

The International Hip Outcome Tool-33 (iHOT-33) is a patient-derived hip-specific patient-reported instrument that measures health-related quality of life in young, active patients with hip disorders. It was developed by a large international collaboration of patients and clinicians led by MAHORN over 5 years. It comprises 33 items, each measured on a visual analogue scale (VAS), to assess functional limitations, sports activities, and job-related and emotional concerns. Importantly, these items were generated and refined by patients, reflecting their most important concerns. The instrument generates a single score in the range of 0 to 100. People with no hip complaints usually score ≥ 95. A diverse international population of younger adults with a variety of hip pathologies had a mean score of 66, with a standard deviation (SD) of 19.3 (Damian R Griffin, University of Warwick, 2021, personal communication).

The iHOT-33 has been validated for use in patients with FAI syndrome and is sensitive to change after treatment. The minimum clinically important difference (MCID) has been determined using an anchor and distribution-based approach in a group of 27 young active patients who were independent of the development population. Clinical change was determined using a global rating scale that asked patients whether their hip condition had improved, had deteriorated or had not changed since the previous assessment, using a single VAS. The MCID was 6.1 points.[33,34]

The iHOT-33 and EQ-5D-5L have been adopted as the principal outcome measures by the UK Non-Arthroplasty Hip Registry. This registry is led by the British Hip Society (London, UK) and its use in all patients having arthroscopic FAI surgery is required by the National Institute for Health and Care Excellence (NICE).[15]

In our pilot study, we tested the Non-Arthritic Hip Score and iHOT-33 as potential primary outcome measures, and found both to be easy to use and acceptable to patients. The extensive patient involvement in item generation, the availability of an independently determined MCID and the use of iHOT-33 as the principal outcome measure for the UK Non-Arthroplasty Hip Registry led us to choose iHOT-33 as the most appropriate primary outcome measure for a full trial.

Develop and test trial procedures

Protocols, eligibility criteria, patient information material and case report forms (CRFs) were designed for the pilot RCT and were available for the full trial. We interviewed 18 patients who had been treated for FAI syndrome to develop patient information sheets. These patient information sheets were scrutinised by a panel of expert patients with FAI syndrome who helped to improve the content and presentation so that they addressed patients' key concerns and information needs, and provided explanations with appropriate language and detail. Twenty-eight clinicians, including surgeons, physicians and physiotherapists, also contributed to developing these procedures and documents.

Research Ethics Committee and national R&D approvals were granted for the pilot trial promptly and without any significant concerns. The majority of the recruitment sites were then able to complete local approval within 1 month of our site initiation visits. Typical causes for a delay to approval were identified within the first few sites, allowing these to be addressed in subsequent sites at a much earlier stage. This may help considerably to ensure that further sites in a full trial can obtain local R&D approval more quickly.

Conclusion of the feasibility study and pilot trial

We showed that a robust RCT of hip arthroscopy compared with best conservative care for patients with FAI syndrome was feasible, that patients and clinicians were willing to participate, that we were able to obtain ethics and R&D approval at multiple sites, and that the trial procedures we developed worked well. The pilot trial recruited successfully (70% recruitment rate) to the protocol that will be used for the full trial and these patients were, therefore, included in the full trial analysis.

Relevance of project

Young adults with hip pain are now often aware of the diagnosis of FAI syndrome. There are many descriptions in scientific literature, popular press and on the internet, but there is an overwhelming focus on the benefits of surgery, with little regard to other treatments.[7,20] With limited evidence of effectiveness and a significant increase in the cost of arthroscopic surgery (with an NHS tariff for hip arthroscopy of £5200), a number of NHS care commissioners have begun to limit the funding for this procedure. In some areas, hip arthroscopy is not commissioned at all and in others, only patients who have failed to respond to non-operative treatments are allowed access to arthroscopic surgery.[21] Provision of non-operative alternatives to surgery for FAI syndrome is inconsistent, and the evidence and guidance for this conservative care is weak.[20] PHT is a credible physiotherapy-led 'best conventional care' protocol for FAI syndrome, developed for the pilot trial through clinical consensus informed by existing literature.[5] This trial will establish the best treatment for patients with FAI syndrome, taking into account clinical effectiveness, costs and risks. This will allow clinicians within the NHS to offer treatment for FAI syndrome that is in patients' best interests. Establishing the comparative cost-effectiveness of arthroscopy and PHT will help NHS commissioners to make funding decisions based on robust evidence and to avoid the current situation of unjustified variation in provision.

Null hypothesis

Our null hypothesis was that there is no difference in the iHOT-33 questionnaire score 12 months following randomisation between adults diagnosed with FAI syndrome treated with arthroscopic hip surgery and adults diagnosed with FAI syndrome treated with best conservative care.

Objectives

The primary objective was to measure the clinical effectiveness of hip arthroscopy compared with best conservative care for patients with FAI syndrome, assessed by patient-reported hip-specific quality of life after 1 year.

The secondary objectives were to:

- compare differences in general health status and in health-related quality of life after 12 months between treatment groups
- compare, in a longitudinal analysis, the pattern of clinical change over 36 months
- compare patient satisfaction with treatment and outcome after 1 year
- compare the number and severity of adverse events (AEs) after treatment
- compare the need for further procedures up to 3 years after initial treatment
- compare the cost-effectiveness of hip arthroscopy for FAI with best conservative care, within the trial and for a patient's lifetime
- develop and report processes to optimise recruitment in a RCT or surgery compared with non-operative care
- measure the fidelity of delivery of interventions.

Chapter 2 Methods

This trial was conducted in accordance with the Medical Research Council's Good Clinical Practice principles and guidelines, the Declaration of Helsinki,[35] Warwick Clinical Trials Unit (WCTU) (Coventry, UK) standard operating procedures (SOPs), relevant UK legislation and the trial protocol. Ethics approval was granted on 1 May 2014 (reference 14/WM/0124) by the Edgbaston Research Ethics Committee (current approved protocol version 4.0, 18 August 2017). The trial was registered as ISRCTN64081839. This project was funded by the National Institute for Health Research Health Technology Assessment programme (feasibility and pilot trial grant number 10/41/02, full trial grant number 13/103/02).

Trial design

We conducted a multicentre, pragmatic, assessor-blinded parallel-arm 1 : 1 RCT of hip arthroscopy compared with conservative care for FAI syndrome, assessing patient pain, function, general health, quality of life, satisfaction and cost-effectiveness. There was an integrated qualitative recruitment intervention (QRI) that included interviews with recruiters and patients, and observations of recruitment appointments, to ensure that patients had the opportunity to fully consider participation in the trial.[28]

We hypothesised that arthroscopic surgery is superior to conservative care at 12 months for self-reported hip pain and function for patients with FAI syndrome. The trial was conducted on consenting patients treated in the NHS. Hospitals participating in the FASHIoN trial had an organised hip arthroscopy service that treated at least 20 patients with arthroscopic surgery for FAI syndrome per year.

Participants

We recruited a cohort of typical patients with FAI syndrome deemed suitable for arthroscopic surgery. This cohort included patients who may have already received a course of physiotherapy.

Inclusion criteria

- Age $\geq$ 16 years (with no upper age limit).
- Symptoms of hip pain (including clicking, catching or giving way).
- Radiographic evidence of pincer- and/or cam-type FAI morphology on plain radiographs and cross-sectional imaging, defined as:
    - cam morphology – an alpha angle > 55°[36]
    - pincer morphology – a lateral centre-edge angle of > 40° or a crossover sign on the anteroposterior radiograph of the pelvis.[37]
- The treating surgeon believes the patient would benefit from arthroscopic FAI surgery.
- The patient is able to give written informed consent and to participate fully in the interventions and follow-up procedures.

Exclusion criteria

- Evidence of pre-existing osteoarthritis, defined as Tönnis grade > 1[38] or a > 2-mm loss of superior joint space width on an anteroposterior pelvic radiograph.[39]

- Previous significant hip pathology, such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis.
- Previous hip injury, such as acetabular fracture, hip dislocation or femoral neck fracture.
- Previous shape-changing surgery (open or arthroscopic) in the hip being considered for treatment.

Screening and recruitment

Participants were recruited from among the patients presenting to young adult hip clinics in each of the centres. Patients who complained of hip pain and who did not already have a diagnosis of hip osteoarthritis were identified as potential participants by screening referral letters to collaborating surgeons. Research nurses/associates kept accurate screening logs to identify whether or not these potential participants met the eligibility criteria. Prior to their appointment, these patients were approached to seek consent for recording of their clinic consultations.

Surgeons assessed patients as usual, taking a history, examining the patient and performing appropriate imaging investigations. Patients in whom a diagnosis of FAI syndrome was made and who met the eligibility criteria received a description of the condition from their surgeon and an explanation that there were two possible treatments: (1) an operation or (2) a package of PHT. Patients were given patient information about FAI syndrome and the trial. Patients were then invited to a trial information consultation to discuss what action they would like to take.

Patients attended a trial information consultation with a trained clinical researcher. Information was again provided about FAI, FAI's possible treatments and the trial. Patients were given an opportunity to ask questions. Patients were then invited to give their consent to become participants in the trial. Patients who wanted to take more time to consider were given an opportunity to do so. Patients who agreed to take part completed baseline questionnaires at this consultation.

Consent

Written informed consent was obtained by a researcher delegated and trained by the research team. In general, patients had at least 1 month from initial consultation to the day of surgery or start of PHT so that there was sufficient time for patients to consider taking part in the trial.

Qualitative research intervention

To optimise recruitment and informed consent, trained qualitative researchers listened to recordings of the surgeons' and RA/nurses' trial information consultations to identify communication patterns that facilitated or hindered patient recruitment.[28] In-depth interviews with the recruiters were undertaken to identify clear obstacles and hidden challenges to recruitment, including the influence of patient preferences and equipoise.[40] Research teams were interviewed to identify clinician equipoise, patient pathways from eligibility to consent and staff training needs at each participating site.[28] Findings were fed back to the chief investigator and Trial Management Group (TMG) so that practice could be reviewed and any necessary changes (including additional training) implemented. The number of eligible patients and the percentages of these patients who were approached and consented to randomisation were monitored at each site.

This research was linked to the Quintet programme of research within the Medical Research Council ConDuCT-II (Collaboration and innovation in Difficult and Complex randomised controlled Trials II) Trial Methodology Hub (Bristol, UK).

Randomisation

Participants were randomised, in a 1 : 1 ratio, to arthroscopic surgery or PHT using a computer-generated sequence. Allocation was made by the research nurse/associate via a centralised telephone randomisation service provided remotely by WCTU. Allocation concealment was ensured, as the randomisation programme did not release the randomisation code until the patient had been recruited into the trial. Research nurses/associates who recruited participants ensured that they were referred for the allocated intervention.

Sequence generation

To improve the baseline balance between intervention group samples, a minimisation (adaptive stratified sampling) algorithm was implemented using study site and impingement type (i.e. cam, pincer or mixed) as factors.

Blinding

The patients could not be blind to their treatment. The treating surgeons were not blind to the treatment, but took no part in outcome assessment for the trial. The functional outcome data were collected and entered onto the trial central database via postal questionnaire by a research assistant who was blind to the treatment allocation. The statistical analysis was also performed blind.

Post randomisation withdrawals

Participants could withdraw from the trial treatment and/or the whole trial at any time without prejudice. If a participant decided to change from the treatment to which they were allocated, they were followed up and data collected as per the protocol until the end of the trial. However, every effort was made to minimise crossovers from both intervention arms. It was made clear to study participants and clinicians that it was important for the integrity of the trial that everyone followed their allocated treatment. For those participants who decided to move to the other intervention arm, the numbers, direction and reasons for moving were recorded and reported in line with CONSORT (Consolidated Standards of Reporting Trials) guidance. The QRI investigated how and why participants made their decision. The QRI team provided training for physiotherapists and surgeons so that they were equipped to answer patients' questions about the trial during treatment. During the pilot trial, we found that this reduced the risk of participants losing confidence in the trial and breaching protocol.

Interventions

The two interventions commenced as soon as possible after randomisation. We recorded the dates of randomisation and the start of allocated treatment. As this was a pragmatic trial, participants were not prohibited from undergoing any additional/concomitant care.

Arthroscopic surgery

An operative protocol was established during and implemented in the pilot trial. The agreed protocol was typical of the surgical techniques used by the majority of surgeons around the world, and representative of those used in the UK. The surgeons delivering the intervention were all NHS consultants.

Preoperative protocol

Patients underwent routine preoperative care, which included an assessment of their general health and suitability for a general anaesthetic.

Perioperative protocol

Arthroscopic hip surgery was performed under general anaesthesia with the patient in a lateral or supine position. Arthroscopic portals were established in the central and peripheral compartment under radiographic guidance and in accordance with the surgeon's usual practice. Shape abnormalities and consequent labral and cartilage pathology was treated. Bony resections at the acetabular rim and the head–neck junction were assessed by intraoperative image intensifier radiograph and/or satisfactory impingement free range of movement of the hip.

Postoperative protocol

Patients were allowed home when they could walk safely with crutches (usually within 24 hours). On discharge, all patients were referred to outpatient physiotherapy services for a course of rehabilitation, as per usual care for that surgeon. We did not specify a protocol for this postoperative physiotherapy, but recorded it using a treatment log. Postoperative physiotherapists were distinct from those providing PHT to avoid contamination between groups. Patients also had a postoperative MRI, which included a proton density volume acquisition sequence (for MRI protocol see *Appendix 1*).

Fidelity assessment

To ensure the fidelity of the surgery and to identify participants for a secondary analysis, a panel of international experts reviewed operation notes, intraoperative images and postoperative MRI scan to assess whether or not adequate surgery was undertaken (see *Appendix 2*). This panel included Mark Philippon (USA; then chairperson of the Research Committee of the International Society for Hip Arthroscopy), Martin Beck (Switzerland; one of the investigators credited with developing the early understanding of FAI), John O'Donnell (Australia; past president of the International Society of Hip Arthroscopy) and Professor Charles Hutchinson (UK; an expert in musculoskeletal radiology). The fidelity assessment process was tested in the pilot trial. The panel rated each surgical case as satisfactory, borderline satisfactory and unsatisfactory (see *Appendix 1*).

Personalised hip therapy

Personalised hip therapy was a package of physiotherapy-led best conservative care for FAI syndrome.[5] It was developed during the feasibility study and 'road-tested' during the pilot trial.[3] Although the name for this intervention was new, the care being offered represented a consensus of what physiotherapists, physicians and surgeons in the NHS provided and regard as 'best conventional care'. PHT was delivered by at least one qualified physiotherapist at each site. To prevent contamination of the treatment groups, the physiotherapists who delivered PHT were distinct from those who delivered postoperative physiotherapy.

Training physiotherapists

Personalised hip therapy physiotherapists were trained in a FASHIoN PHT workshop and supported by the physiotherapy lead and research facilitator (NF and JS).

We developed and tested the 1-day workshop during our pilot trial. Following the initial PHT workshops during the feasibility study, the remaining workshops were delivered through the recruitment period from November 2014 to March 2016. The workshops included lectures, presentations, discussion of real cases and working through PHT progressions. A PHT manual and exercise sheets (for patients) were provided to all the PHT physiotherapists (see *Appendix 1*). Ongoing training and support was provided by the physiotherapy research facilitator and this included an initial site visit and monitoring visits. The purpose of the initial visit was to ensure that the treating physiotherapist fully understood the detail of PHT. The first visit was scheduled to occur after the first patients were randomised to PHT and before

they had started treatment. Monitoring visits provided opportunities for further training and to conduct a source verification audit (see *Fidelity assessment*). Although PHT offered a framework to deliver best conservative care, the treatment was not a fully standardised regime. Physiotherapists were trained and encouraged to tailor their treatment to each patient, focusing on deficiencies identified in their assessment and based on the patients' progression.

Pre treatment

Participants received a PHT information pack (see *Appendix 1*) that described what to expect during the course of their treatment. The first core component of PHT was an assessment of pain, function and range of hip motion.

Treatment

Personalised hip therapy had three further core components: (1) an exercise programme that had the key features of individualisation, progression and supervision; (2) education; and (3) help with pain relief (which may have included one X-ray or ultrasound-guided intra-articular steroid injection if pain prevented performance of the exercise programme). The intervention was delivered over a minimum of 12 weeks, with a minimum of six patient contacts. Some of the patient contacts were permissible using either telephone/e-mail for whom geographical distance prevented all contacts being carried out face to face. The number and frequency of the treatment sessions was at the discretion of the physiotherapist and was informed by the patients' deficiencies and progression.

Post treatment

Typically, PHT was delivered over a minimum of 12 weeks. However, in situations in which the patient needed additional review, support or guidance, further sessions with the physiotherapists were permitted up to a maximum of 10 sessions over 6 months.

Fidelity assessment

To assess the accuracy of the PHT CRFs a source verification audit was undertaken to compare the physiotherapists' hospital notes and the PHT CRF. Source verification was undertaken at each site and with 10% of cases sampled. The CRFs were graded as either a satisfactory or unsatisfactory reflection of the hospital notes. The source verification was undertaken by the physiotherapy research facilitator (JS). The findings of the source verification audit were fed back to the fidelity assessment panel.

The PHT CRFs were assessed to determine the fidelity of each intervention and to identify participants for a secondary analysis. This assessment was completed by the panel that developed the protocol for PHT, including Nadine Foster (Senior Academic Research Physiotherapist), Ivor Hughes and David Robinson (UK; Extended Scope Musculoskeletal Physiotherapists) and Peter DH Wall (Academic Orthopaedic Surgeon).

Treatment was rated as satisfactory, borderline or unsatisfactory. The panel assessed whether or not a sufficient number of treatments had occurred (at least six sessions in 12 weeks, but fewer than 10 sessions in 6 months), whether or not the treatment included all four core components of PHT and whether or not the exercise programme was individualised, supervised and progressive.

Treatment crossover

Crossover of participants between interventions can be problematic in trials of this nature. To minimise this, care was taken prior to enrolment in the trial to ensure that potential participants:

- were willing to receive either intervention
- understood that both treatments were thought to provide benefit
- were willing to remain with their allocation for 12 months
- understood that both interventions may take 6 months to improve symptoms.[39,41]

In instances where patients were not satisfied with how their treatment was progressing prior to reaching the primary outcome, they were able to have a further consultation with their treating surgeon where they were treated in their best interests.

Outcomes

Baseline data were collected from participants once consent was obtained and prior to randomisation. Follow-up questionnaires were administered centrally by a data clerk via post. If participants failed to respond, they were contacted via telephone, e-mail or via their next of kin, where necessary.

Primary outcome

The primary outcome was hip pain, function and hip-related quality of life measured using the iHOT-33 at 12 months following randomisation. The iHOT-33 is a validated hip-specific patient-reported outcome tool that measures health-related quality of life in young, active patients with hip disorders.[31] The iHOT-33 consists of the following domains: symptoms and functional limitations, sports and recreational activities, job-related concerns and social, emotional and lifestyle concerns.

We chose it following our feasibility and pilot study, as it is more sensitive to change than other hip outcome tools, it does not show evidence of floor or ceiling effects in patients undergoing hip arthroscopy and patients were involved extensively in item generation and, therefore, we can be confident that it measures what is most important to patients. The iHOT-33 has an independently determined MCID. The iHOT-33 is also used as the principal outcome measure for the UK Non-Arthroplasty Hip Registry, which is mandated for arthroscopic FAI surgery by NICE.[15,31]

Secondary outcome measures

Health-related quality of life: EuroQol-5 Dimensions, five-level version

The EQ-5D-5L is a validated measure of health-related quality of life, consisting of a five-dimension health status classification system and a separate VAS. EQ-5D-5L is applicable to a wide range of health conditions and treatments, and provides a simple descriptive profile and a single index value for health status.[42] Responses were converted into health utility scores using established algorithms.[43]

General health: Short Form questionnaire-12 items

The Short Form questionnaire-12 items (SF-12) is a validated and widely-used health-related quality-of-life measure that is used for hip conditions and treatments.[44] SF-12 is able to produce the physical and mental component scales originally developed from the Short Form questionnaire-36 items with considerable accuracy, but with far less respondent burden.[45] Responses were converted into health utility scores using established algorithms.[46]

Patient satisfaction

Patient satisfaction was measured using questions that our team (NF) had used in previous trials with musculoskeletal pain patients.[47] We measured two distinct dimensions of satisfaction in all participants during follow-up: (1) 'overall, how satisfied are you with the treatment you received?' and (2) 'overall, how satisfied are you with the results of your treatment?' Responses were on a five-point Likert scale.

Qualitative assessment of outcome

We conducted in-depth one-to-one interviews with a purposively selected sample of 25–30 participants in each of the trial groups. These samples included older and younger, male and female, more and less active, and more and less satisfied participants recruited at different trial sites. The qualitative interviews supplement the quantitative outcomes. Interviews explored experiences of the trial processes, the treatments and the consequences of treatment to participants' lives, health and well-being.

Adverse events

We recorded the number and type of AEs up to 12 months. Any AEs were reported on the appropriate CRF and returned to WCTU. Any serious adverse events (SAEs) were faxed to WCTU, within 24 hours of the local investigator becoming aware, where the chief investigator determined causality and expectedness. SAEs deemed unexpected and related to the trial were reported to the Research Ethics Committee within 15 days.

Resource utilisation

Information on health-care resource use was collected by incorporating questions within the patient follow-up questionnaires. We confirmed the feasibility and acceptability of this approach in our pilot trial. In addition, patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.[48]

Need for further procedures

We recorded any further treatments performed in both groups, such as hip arthroscopy, open hip preservation surgery, hip replacement or additional 'out-of-trial' physiotherapy. We ascertained the need for further procedures by questionnaire at 2 and 3 years. In addition, we also propose a 5- and 10-year no-cost ascertainment of hip replacement by linkage to the UK National Joint Registry and Hospital Episode Statistic databases.

Follow-up

The follow-up schedule is outlined in *Table 1*. The primary outcome was collected 12 months following randomisation.

Adverse event management

Adverse events are defined as any untoward medical occurrence in a clinical trial patient that do not necessarily have a causal relationship with the treatment. All AEs were listed on the appropriate CRF and returned to the FASHIoN trial central office.

TABLE 1 Data collection time points

Time point	Data collection
Baseline	Demographics, physical activity (UCLA Activity Scale),[49] iHOT-33, SF-12, EQ-5D-5L, preoperative imaging and economics questionnaire
Intervention	Operation notes and photographs or PHT log, complications records 6 weeks post start of intervention and postoperative MRI (surgery intervention only)
6 months	iHOT-33, SF-12, EQ-5D-5L, resource utilisation and AEs
12 months (primary outcome)	iHOT-33, SF-12, EQ-5D-5L, patient satisfaction, resource utilisation and AEs
2 years	iHOT-33, EQ-5D-5L and further procedures questionnaire
3 years	iHOT-33, EQ-5D-5L and further procedures questionnaire
5 and 10 years	Linkage to the National Joint Registry and Hospital Episode Statistics to identify need for hip replacement

UCLA, University of California, Los Angeles.

Serious adverse events are defined as any untoward and unexpected medical occurrences that:

- result in death
- are life-threatening
- require hospitalisation or prolongation of existing inpatients' hospitalisation
- result in persistent or significant disability or incapacity
- are a congenital anomaly or birth defect
- are important medical conditions that, although not included in the above, may require medical or surgical intervention to prevent any of the outcomes listed above.

All SAEs were entered onto the reporting form and faxed to WCTU within 24 hours of the investigator becoming aware of them. Once received, causality and expectedness was confirmed by the chief investigator. The Research Ethics Committee were notified, within 15 days, of SAEs that were deemed to be unexpected and related to the trial. All such events were reported to the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) at their next meeting.

Serious adverse events that were expected as part of both interventions are listed in *Risks and Benefits* below. All participants who experienced SAEs were followed up as per protocol until the end of the study period.

Risks and benefits

Both interventions were thought to provide benefit in patients with FAI syndrome. The short-term risks of the study related to the two interventions. These risks are described below and informed the expected SAEs.

Arthroscopic surgery

Hip arthroscopy requires a general anaesthetic. The risk of complications from hip arthroscopy is about 1–2% and these include the following:

- Infection, which is thought to occur in less than 1 in 1000 patients.
- Bleeding, possibly causing bruising or a local haematoma.
- Traction-related complications. (To perform hip arthroscopy, traction is required to separate the hip joint surfaces. Sometimes after the procedure, the pressure from the traction can cause some numbness in the leg, but the numbness usually resolves within a few hours or days.)
- Osteonecrosis. (During surgery, the blood supply to the hip joint could be damaged; however, there are no reported cases of osteonecrosis following arthroscopic FAI surgery.)
- Femoral neck fractures. (This is also a very rare complication and would require a further procedure to fix the fracture.)

Personalised hip therapy

There are some small risks with pain medications and joint injection. However, the main risk is muscle soreness and transient increases in pain from the exercises that were undertaken.

Statistical analysis

The primary analysis was the difference, at 12 months, in hip-related quality of life (using the iHOT-33) between the two treatment groups, blinded, on an intention-to-treat basis and presented as the mean difference between the trial groups with a 95% confidence interval (CI). The iHOT-33 data were assumed to be normally distributed after appropriate variance-stabilising transformation.

The minimisation randomisation procedure should have ensured treatment group balance across recruiting sites. We had no reason to expect that clustering effects would be important for this study, but the possibility of such effects was explored as part of the analysis. We planned to account for clustering by generalising a conventional linear (fixed-effects) regression approach to a mixed-effects modelling approach where patients are naturally grouped by recruiting sites (random effects) and, if amenable to analysis, also by physiotherapist and surgeon. This model formally incorporated terms that allowed for possible heterogeneity in responses for patients due to the recruiting centre, in addition to the fixed effects of the treatment groups and patient characteristics that may prove to be important moderators of treatment effect, such as age, sex and FAI type. The analysis was conducted using specialist mixed-effects modelling functions available in the software packages Stata® release 14 (StataCorp LP, College Station, TX, USA) and R (The R Foundation for Statistical Computing, Vienna, Austria). All tests were two sided and were considered to provide evidence for a statistically significant difference if *p*-values were < 0.05 (i.e. a 5% significance level).

Secondary analyses was performed using the above strategy for other approximately normally distributed outcome measures, including iHOT-33 at 6 months, SF-12 (and computed subscales) and EQ-5D-5L. Differences in dichotomous outcome variables, such as AEs, complications related to the trial interventions and the need for further procedures, were compared between groups using chi-squared tests (or Fisher's exact test) and mixed-effects logistic regression analysis, adjusting for the stratifying variables, with differences between trial intervention groups quantified as odds ratios (and 95% CIs). The temporal patterns of AEs were presented graphically and, where appropriate, a time-to-event analysis (Kaplan–Meier survival analysis) to assess the overall risk and risk within individual classes of AEs. Ordinal scores for patient satisfaction were compared between intervention groups using proportional odds logistic regression analysis, assuming that the estimated intervention effect between any pair of categories is equivalent.

Our inferences were drawn from the intention-to-treat analysis. We performed two exploratory secondary analyses. One exploratory analysis compared patients who received surgery with those who received conservative care. A second exploratory analysis compared patients randomised to surgery and PHT and who received treatment deemed to be of a high fidelity by the respective review panels. We performed a subgroup analysis by FAI type because it was possible that treatment effect is moderated by type. We anticipated that adequate steps were taken to prevent crossovers from being a major issue in this study. Therefore, we expected the main intention-to-treat analysis to provide definitive results. An independent DMC monitored crossovers and adherence to treatment and advised on appropriate modifications to the statistical analysis plan as the full progressed.

The feasibility and pilot studies[2,3] were designed explicitly to assess feasibility and measure recruitment rates, and not to estimate treatment effectiveness. Data from the pilot were pooled with data from the full trial, and analysed together.

Sample size

The development work for iHOT-33 reported a mean iHOT-33 score of 66 (SD 19.3) in a heterogeneous population with a variety of hip pathologies. The baseline iHOT-33 data from our pilot trial suggests that the target population of patients being considered for hip arthroscopy for FAI in the UK have lower scores with less variability than the heterogeneous population, with a mean score of 33 (SD 16).

During our feasibility study, we estimated the likely effect size of hip arthroscopy compared with best conventional care for FAI to be 0.5. The MCID for iHOT-33 in this population is 6.1 points. Our sample size calculation is, therefore, based on a SD of 16 and a MCID of 6.1 (i.e. a standardised effect difference between groups at 12 months of 0.38).

Table 2 shows the expected sample size for scenarios with 80% and 90% power to detect an effect of this size, at a 5% significance level, assuming an approximately normal distribution of the iHOT-33 score. *Table 2* also shows sample sizes for small to moderate (0.32) and moderate (0.47) effect differences, which are broadly consistent with other pragmatic RCTs measuring clinical effectiveness.

A systematic review of observational studies[50] reported effect sizes of hip arthroscopy for FAI of between 0.67 and 2.95 up to 5 years after surgery, but these are likely to be overestimates of the real effect we might measure in this trial. These observational studies were uncontrolled studies, and we anticipate that our best conventional care protocol will provide some benefit.

We have, therefore, adopted a conservative approach, seeking to demonstrate an effect difference between groups equal to the MCID. We proposed to recruit sufficient patients to be able to analyse 292 patients at the 12-month follow-up. Allowing for 15% loss to follow-up, we aimed to recruit a sample of 344 participants (i.e. 172 participants in each group). This would provide 90% power to detect a difference of 6.1 iHOT-33 points, if that is the true difference.

Analysis plan

A full statistical analysis plan was developed and approved by the trial statistician(s) and the chief investigator. This plan was also reviewed by the DMC once finalised, in line with the SOPs at WCTU.

Software

All routine interim data reports and final statistical analyses were conducted using Stata 14. A bespoke secure database was created by the programing team at WCTU to enter, store and maintain all trial data and monitor them for accuracy and integrity. A secure Open Database Connectivity data link was used to obtain data when necessary, and data export was restricted to only those members of the trial team who required access for analysis purposes.

Data validation

A FASHIoN data monitoring plan was developed at the outset of the study. The plan covered all aspects of data collection, including data entry, receipt, storage, checking, security and transfer.

Monitoring of data collection was also conducted by the independent DMC, which received regular reports on data quality and completeness as part of its ongoing support to the study. Prior to the final analysis, data were checked for outliers and missing data. Outcome data were validated using defined score ranges for each measure. Any queries were reported to the trial co-ordinator who liaised with the relevant recruiting centre, if appropriate. All subsequent changes to the data were recorded in accordance with the relevant SOP and the FASHIoN data management plan.

TABLE 2 Sample size calculations for variable combinations of power and SD estimates

	Power		
SD	80%	90%	Standardised effect difference
13.3	144	192	0.47
16.0	218	292	0.38
19.3	316	422	0.32

Missing data

Data were not available because of withdrawal of patients, lack of completion of individual data items and loss to follow-up. Reasons for missing data were ascertained and reported as far as possible. Any patterns of missing data were carefully considered, including, in particular, whether or not data could be treated as missing completely at random. No formal statistical testing was planned to assess missing data, but model assumptions were checked and patterns explored. If judged appropriate, missing data in the primary outcome (iHOT-33) were imputed using an imputation procedure in Stata (from the mi set of commands). Any imputed data were on an individual item level, as opposed to an overall score level. Reasons for ineligibility, non-compliance, withdrawal or other protocol violations and deviations are stated, and any patterns summarised, in *Chapter 4*.

Interim analyses

There were no pre-planned interim data analysis for the FASHIoN study, and the study sample size and design were powered only for the final analysis.

Exploratory analysis

A post hoc unplanned exploratory analysis was undertaken to investigate the effect of the timing of treatment on the primary outcome, an issue that was not identified prior to study design and conception. The most appropriate approach was to include an additional binary covariate in the model, which indicated whether treatment was early (< 12 weeks) or late (> 12 weeks) and assess whether or not the inclusion of this covariate improved the model fit and had an impact on the size and interpretation of the treatment effect.

Economic evaluation

Overview

A prospective within-trial cost–utility analysis was conducted to estimate the cost-effectiveness of arthroscopic surgery compared with PHT as treatment options for FAI syndrome. Costs were expressed in GBP (2016 price year) and health outcomes in quality-adjusted life-years (QALYs). The base-case analysis was based on the intention-to-treat population and conducted from the perspective of UK NHS and Personal Social Services. The time horizon covered the period from randomisation to end of follow-up at 12 months post randomisation. Costs and outcomes were not discounted because of the short 1-year time horizon adopted for this within-trial evaluation. Sensitivity and subgroup analyses were conducted to investigate the likely impact of alternative data inputs and assumptions on cost-effectiveness, and identify subgroups most likely to benefit from treatment. Findings are reported in accordance with the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) guidelines.[51]

Measurement of resource use and costs

Data were collected on (1) resource use and costs associated with delivery of the interventions, (2) health and social care service use during the 12 months of follow-up and (3) broader societal resource use and costs (e.g. private medical costs and lost productivity costs, such as lost income over the 12 months of follow-up).

Cost of personalised hip therapy

Personalised hip therapy was delivered to trial participants primarily by experienced physiotherapists (grade 7 and above) within NHS hospital outpatient clinics. The number and duration of PHT sessions attended were recorded for all patients who received this intervention. The unit cost of a band 7 hospital physiotherapist (including qualifications and overheads) was obtained from the Personal Social

Services Research Unit (PSSRU) *Unit Costs of Health and Social Care 2016*[52] and was £55 per hour. Unit costs were multiplied by duration of physiotherapy contact (in minutes) and summed across sessions attended to give total treatment costs per patient. Indirect costs associated with delivery of the intervention, such as use of the treatment room facility, administrative support and overheads, are taken into account in PSSRU unit cost calculations and, therefore, separate costs for these were not included in our estimate of PHT costs.

Cost of surgery

A micro-costing exercise was undertaken to estimate resource use and costs associated with delivery of arthroscopic surgery for FAI. Resource use data were collected for a subsample of trial participants who had received the surgery using a specially designed costing questionnaire that captured the following items:

- duration of surgery
- post-surgical inpatient length of stay
- number, specialty and grade of clinical staff involved in the surgical procedure
- quantity and type of disposable arthroscopic equipment and/or implants used.

Surgery time was defined from start of anaesthesia to time patient left the operating room on completion of surgery. Inpatient length of stay was counted as 1 day if the patient was admitted and discharged on the same day, 2 days if the patient was discharged the next day and so on, which is in line with NHS reference costing methodology.[53] Anaesthetic drugs and associated consumables, such as syringes and needles, were collected separately during a sample of operations and assumed to be the same for all patients who had the surgery.

Total cost of surgery was calculated for each patient by summing across the following five categories: (1) staff time, (2) theatre use in hours, (3) disposal surgical equipment, (4) anaesthetic drugs and disposables and (5) post-surgery inpatient bed-days. Operating room/theatre running costs were estimated based on data published by Information Services Division (Edinburgh, UK).[54] The Scottish data reported total number of theatre hours used and total allocated costs across NHS hospitals in Scotland for the 2015–16 financial year. Allocated costs are defined to include expenditure on non-clinical staff, property and equipment maintenance, domestics and cleaning, utilities, fittings and capital expenditure, and excluded clinical staff costs.[55] The hourly running cost of an operating room/theatre was obtained by dividing the total allocated costs per year by the total theatre time (in hours) per year.

Unit costs of clinical staff time were obtained from the PSSRU *Unit Costs of Health and Social Care 2016*[52] compendium. As stated above, these unit costs already factor in direct cost of staff salaries and employer oncosts and training costs, as well revenue and capital overheads, administrative support, office space and work-related travel. The cost of disposal surgical equipment and implants were primarily obtained from the 2016 online edition of the NHS supply chain catalogue.[56] When cost data were not available from the NHS catalogue, procurement department unit costs from the University Hospital Coventry and Warwickshire (Coventry, UK) were applied (Felix Achana, University of Warwick, 2012, personal communication). Cost of anaesthetic drugs were obtained from the prescription costs analysis database.[53]

Resource use during follow-up

Health and social care service use were collected from trial participants for the 3-month period prior to randomisation (to establish baseline data) and the 1-year period post randomisation. Resource use data were collected at three assessment points (i.e. baseline and 6 and 12 months post randomisation) and included:

- details of hospital inpatient and day case admissions
- details of outpatient and accident and emergency attendances
- primary/community care encounters

- use of personal social care services (e.g. Meals on Wheels, laundry services and social care contacts)
- prescribed and over-the-counter medication use
- supplied or self-purchased walking aids, such as crutches and walking sticks, and adaptations to home or work environments
- any other additional costs incurred by patients and their families as a result of their hip pain, including private medical costs and out-of-pocket expenditures (e.g. travel costs by patients and family members), child care costs and lost income.

Resource inputs were valued by attaching unit costs derived from national compendia to resource inputs.

Hospital-based services included inpatient admissions, day care, outpatient and accident and emergency attendances, and diagnostic tests and scans. Unit costs for these services were obtained primarily from the 2015/16 NHS reference costs main schedules.[57] Per diem costs were calculated for each inpatient admission as a weighted average of Healthcare Resource Group (HRG) codes of related procedures and/or clinical conditions. For example, the average cost per day for inpatient stay in an orthopaedic ward with procedures carried out on the hip/leg was calculated as a sum total of the weighted average of lower limb orthopaedics (trauma) HRG codes divided by average length of stay across elective and non-elective inpatient services.

Primary and community health and social care services included face-to-face or telephone contacts and/or home visits by a general practice doctor, practice nurse, community physiotherapy or other community health or social care professionals. Consultation costs were derived from the PSSRU *Unit Costs of Health and Social Care 2016*[52] compendium.

The cost of private physiotherapy and other private medical costs were obtained from online sources and referenced appropriately in the unit cost tables.

The cost of prescribed medication was obtained primarily from the prescription cost analysis database[53] and electronic searches of the *British National Formulary* (BNF) 2016 edition.[58] Typical dosage and duration of treatment reported in the BNF for each medication were used in calculating quantity of individual preparations if the daily dose and/or duration of the course of medication were not reported. The quantity of over-the-counter medicines were rounded to the nearest pack and unit costs obtained from online sources.

The cost of walking aids and adaptations were either provided by the patients themselves (if self-purchased) or taken from the NHS supply chain catalogue[56] if supplied by a health provider during the trial follow-up period. It was assumed that walking aids, such as crutches, sticks, grab rails, dressing aids and specially adapted shoes, were supplied as part of treatment if the cost of purchase were not provided by trial participants.

Patient-level costs were generated for each resource variable by multiplying the quantity reported by the respective unit cost weighted by duration of contact, when appropriate. Summary statistics were generated for resource use variables by treatment allocation and assessment point. Between-treatment group differences in resource use and costs at each assessment point were compared using the two-sample *t*-test. Statistical significance was assessed at the 5% significance level. Standard errors (SEs) are reported for treatment group means and bootstrap 95% CIs for the between-group differences in mean resource use and cost estimates.

Measurement of outcomes

The health-related quality of life of trial participants was assessed at baseline and at 6 and 12 months post randomisation using the EuroQol-5 Dimensions, three-level version (EQ-5D-3L) in the feasibility study, the EQ-5D-5L in the main trial and the SF-12 in both feasibility and main trial samples.[59–61] Responses to each health dimension were categorised as optimal or suboptimal with respect to

function, with optimal level of function indicating no impairment (e.g. 'no problem' on the EQ-5D-3L dimensions) and suboptimal indicating any functional impairment. Between-group differences in optimal and suboptimal level of function for each health dimension were compared for each outcome measure using chi-squared tests.

The responses to each health-related quality-of-life instrument were converted into health-related quality-of-life weights (also referred to as utility weights) using established algorithms for each instrument. Utility values were generated using the UK value set for the EQ-5D-3L, the interim crosswalk value set for mapping from the EQ-5D-5L to the EQ-5D-3L, the newly published EQ-5D-5L tariffs for the EQ-5D-5L and the Short Form questionnaire-6 Dimensions (SF-6D) tariff based on SF-12 responses.[46,62–64]

Quality-adjusted life-years were generated for each patient using the area under the baseline-adjusted utility curve, assuming linear interpolation between the three utility measurements. QALYs were generated for patients in the feasibility sample using utilities derived from EQ-5D-3L and SF-6D tariffs and for those in the main study sample using the EQ-5D-5L crosswalk tariff, the new UK EQ-5D-5L tariff and the SF-6D tarrif.[46,62–64] Health utility values and QALYs accrued over the 12-month follow-up were summarised by treatment group and assessment point and presented as means and associated SEs. Between-group differences were compared using the two-sample *t*-test, similar to the summary analyses of resource inputs and costs.

Cost-effectiveness analysis methods

Missing data

Multiple imputation by chain equations implemented through the MICE package in R was used to handle missing costs and health utility data at each assessment point. Multiple imputation avoids problems associated complete-case analyses, is consistent with good practice and requires data to be missing at random only.[65] Appropriateness of this missing-at-random assumption was assessed by comparing the characteristics of patients with and without missing costs and health-related quality-of-life data at each follow-up time point. Imputations were generated separately by treatment group, as recommended by Faria *et al.*,[66] using the predictive mean matching method, which has the advantage of preserving non-linear relationships and correlations between variables within the data. Twenty imputed data sets were generated and the analyses were fitted to each imputed data set. The results from the 20 data sets were then combined using Rubin's rules. The imputation, analysis and pooling of results steps were performed simultaneously within the MICE package. The imputed data were used to inform the base case and all subgroup and sensitivity analyses, with the exception of one sensitivity analysis, which was conducted using only complete data.

Base-case cost-effectiveness analysis

The base case took the form of an intention-to-treat analysis conducted from a UK health and social service perspective. Health outcomes were expressed in QALYs using utilities generated from the EQ-5D-3L (for feasibility study participants) and the EQ-5D-5L to EQ-5D-3L crosswalk tariff (for the main trial participants). Total costs accrued over 12 months of follow-up were calculated for each patient by summing the delivery costs of the intervention(s) received (irrespective of treatment allocation) and a sum total of follow-up costs reported at the 6- and 12-month assessment points relevant to the perspective of interest. For example, if a patient allocated to the surgery arm of the trial had PHT rather than surgery, then the treatment costs assigned would be the costs associated with delivery of the PHT intervention.

The cost of PHT was calculated by multiplying the unit cost of physiotherapy with the duration of contact (in minutes) and summed across all sessions attended. The cost of surgery was obtained from the micro-costing exercise carried out to estimate resource use and costs associated with the delivery of hip arthroscopy. Patients who had surgery were assigned treatment costs simulated from a normal distribution, with mean and variance estimates obtained from the surgery costing exercise. To avoid double counting treatment costs, self-reports of outpatient physiotherapy attendance (for treatment of lower limb problems) during follow-up were excluded from the total cost calculations for those in the

PHT group (as these would have been included in the estimation of PHT costs). Similarly, self-reports of orthopaedic inpatient admissions (for the category 'your hip/leg') by those who had the surgery were excluded if one admission episode was reported during follow-up. When more than one orthopaedic inpatient stay was reported during follow-up, then the first admission episode was excluded in the total cost calculations and the remainder countered as repeat admissions.

Broader societal costs were also calculated (and used in sensitivity analyses) by adding to the health and social care costs, private medical costs and relevant indirect costs, such as lost income and purchase of specialised equipment.

Two seemingly unrelated normal error regressions were fitted to the data using the systems fit implementation in R. These regressions were used to simultaneously estimate incremental costs and benefits of surgery compared with PHT while accounting for correlation between the two. The regressions controlled for treatment allocation, age, sex, recruitment site, type of impingement, baseline costs (regression equation for costs only) and baseline health-related quality of life (regression equation for outcomes). The incremental cost-effectiveness ratio (ICER) was calculated by dividing the between-group difference in adjusted mean total costs by the difference in adjusted mean QALYs. The cost-effectiveness of hip arthroscopy was determined by comparing the ICER value with cost-effectiveness thresholds of £20,000 and £30,000 per QALY gained, in accordance with NICE recommendations,[67] and to the recent empirical £13,000 per QALY estimate suggested by Claxton *et al.*[68] The incremental net (monetary) benefit of the surgery compared with PHT was calculated for a range of cost-effectiveness thresholds. Net benefit values reflect the opportunity cost of (or the benefits forgone from) adopting a new treatment when resources could be put to use elsewhere. A positive net benefit would suggest that, on average, the new treatment provides net gain compared with the alternative, and can be considered cost-effective at the given cost-effectiveness threshold.

Uncertainty around the mean cost-effectiveness estimates was characterised through a Monte Carlo method.[69] This involved simulating 1000 replicates of the ICER from a joint distribution of the incremental costs and QALYs and plotting the simulated ICERs on the cost-effectiveness plane. Cost-effectiveness acceptability curves were also plotted to give graphical displays of the probability that surgery is cost-effective across a wide range of cost-effectiveness thresholds.

Sensitivity analyses

Sensitivity analyses were conducted to investigate aspects of study design and data collection for which alternative methods existed, but where there was uncertainty regarding which method or approach was best. For example, the cost of surgery was estimated based on data from a subsample of patients who had the surgery in the study. Surgery costs could also be obtained through the HRG case-mix method. Other sensitivity analyses included broadening the perspective of the analysis to capture wider societal costs and their impact on relative cost-effectiveness of the interventions. A list of all sensitivity analyses carried out are presented in *Table 3*.

Subgroup analyses

Heterogeneity in cost-effectiveness estimates was explored through the following subgroup analyses:

- recruitment period (feasibility vs. main trial samples)
- type of impingement (cam vs. mixed/pincer)
- sex (female vs. male).

Longer-term modelling

Given the known limitations of within-trial economic evaluations, the study protocol had allowed for long-term economic modelling to be conducted if the within-trial economic evaluation suggested surgery to be clinically effective and likely to be a cost-effective treatment for FAI.[70] The model would have estimated the long-term (i.e. lifetime) costs and consequences of surgery and assessed whether or not any short-term benefits are sustained over the medium to long term.

TABLE 3 List of sensitivity analyses considered

Sensitivity analysis	Description of changes to base case considered in sensitivity analysis
1	Unadjusted analysis
2	Complete-case analysis
3	Per protocol sample 1: restricted analysis to patients who received allocated treatment
4	Per protocol sample 2: restricted analysis to patients whose surgery or PHT was deemed to be of good quality, as assessed by clinical panel
5	Altering the cost of surgery from £3042 (estimate from the micro-costing) to £2680 based on HRG code HT15Z (Minor Hip Procedures for Trauma, elective long stay)
6	Altering the cost of surgery from £3042 (estimate from the micro-costing) to £5811 based on HRG code HT12A (Very Major Hip Procedures for Trauma with CC Score 12+, elective long stay)
7	Adopting a societal perspective that includes both direct health and social care costs and broader societal costs
8	Use QALYs generated using the SF-6D utility algorithm

Research Ethics Committee approval

The trial obtained approval from the Nation Research Ethics Committee West Midlands – Edgbaston (14/WM/0124) on 1 May 2014 and has been registered with the International Standard Randomised Controlled Trial Number ISRCTN64081839.

Trial Management Group

The TMG oversaw the study and included a multidisciplinary team of clinicians and researchers who had considerable expertise in all aspects of design, running, quality assurance and analysis of the trial. The TMG team met monthly to assess the study progress. The TMG comprised:

- Professor Damian Griffin (chief investigator, trauma and orthopaedic surgeon)
- Mrs Rachel Hobson (study manager)
- Ms Jaclyn Brown (senior project manager)
- Dr Nick Parsons (statistics)
- Mr James Griffin (statistics)
- Professor Stavros Petrou (health economics)
- Mr Felix Achana (health economics)
- Professor Nadine Foster (PHT lead)
- Mr Peter Wall (co-applicant, orthopaedic registrar)
- Dr Marcus Jepson (qualitative research)
- Dr Alba Realpe (qualitative research fellow)
- Mr Edward Dickenson (surgical research fellow)
- Professor Charles Hutchinson (co-applicant, imaging)
- Joanna Smith (physiotherapy research fellow)
- Siobhan Stevens (clinical trial administrator).

Trial Steering Committee

A TSC with an independent chairperson and a ‘lay’ representative was set up. Meetings were held at regular intervals determined by need, but no less than once per year.

The remit of the TSC was to:

- monitor and supervise the progress of the trial towards its interim and overall objectives
- review, at regular intervals, relevant information from other sources
- consider the recommendations of the DMC
- inform the funding body on the progress of the trial.

The TSC comprised:

- Professor Ashley Blom (chairperson)
- Alan Girling (independent member)
- Mr Richard Villar (independent member)
- Professor Damian Griffin (chief investigator)
- Mrs Rachel Hobson (study manager)
- Dr Nick Parsons (statistician)
- James Griffin (trial statistician)
- Mr Jeremy Fry (lay representative)
- Mr David Ralph (lay representative)
- Mrs Ceri Jones (research network representative)
- Mr Matthew Gane (sponsor representative).

Data Monitoring Committee

All data collected in this trial were entered into a secure trial database held at WCTU. All data collected were anonymised after the collection of baseline demographic data and all participants were given a unique trial number. Identifiable participant data were held in a locked filing cabinet and coded with a trial participant number to tag identifiable data to the outcome data. The WCTU quality assurance manager undertook audits of trial records in accordance with WCTU SOPs.

A DMC was established and comprised members who were independent of the sponsor and who did not have competing interests. The DMC reviewed trial progress, interim data and safety aspects of the trial. The DMC also reviewed the statistical analysis plan. Any recommendations were fed back to the TSC by the DMC chairperson. Outcomes were not analysed until all primary outcome data were collected.

The DMC comprised:

- Professor Lee Shepstone (chairperson)
- Professor Simon Donell
- Dr Nicholas Mohtadi.

Patient and public involvement

Patients were heavily involved in the development of the trial protocol during the feasibility and pilot studies. Patient groups helped generate the patient information sheet and a patient representative sat on the TSC. Patient representatives helped to inform the trial dissemination plan, including website information, *Plain English Summary*, a video [URL: https://warwickorthopaedics.org/hip/2018/ukfashion.php (accessed 27 September 2021)] and a dissemination event. Additional patients were invited to attend the trial dissemination event and contributed to extensive discussion. Patients contributed to this report and are listed as authors.

Chapter 3 Qualitative research to improve recruitment and to assess outcomes

This chapter reports an integrated qualitative research intervention conducted in parallel with the main trial. The intervention was based on the Quintet recruitment intervention.[71] This research followed up the work we undertook during the pilot trial and expanded the scope to cover all participating sites in the full trial.[28]

In the following sections, we report the two phases of the QRI. The first phase aimed at understanding recruitment to a trial as it happened. The second phase was the implementation of action plans developed on the basis of the first phase results. A third section of the chapter contains an evaluation of the QRI, comprising a report on the achieved recruitment rates and the results of a survey of FASHIoN recruiters after the recruitment period finished.

Understanding recruitment as it happened

Optimal procedures for site set up and recruiter training were identified at the end of the internal pilot. The TMG used these procedures to guide site teams in setting up their site for participation in the full trial. The details are described below.

Randomised controlled trial set up

We identified system features associated with successful recruitment, including:

- having a dedicated RA in attendance at clinics
- dividing recruitment information between the recruitment surgeon and the RA
- ensuring that referred patients arrived with expectations of receiving treatment for FAI, not necessarily having surgery
- running specific clinics for the target population.

During site initiation visits, the TMG and site research teams discussed how feasible these activities were at their site. Staff at most sites organised clinics that allowed RAs to be present and share the screening and approaching tasks with the recruiting surgeon. Referral letters and information about their diagnosis were modified to manage patient expectations. However, not many sites were able to host specific clinics for the target population.

Recruiter training

Analysis of pilot recruitment consultations pioneered in previous work[72–76] led to the development of a six-step model (*Figure 1*). The objectives of the model were to improve informed consent and encourage participation in the FASHIoN trial.[3] This model guided the development of a recruiter training programme, which is explained in *Action plans to promote informed consent and improve recruitment*.

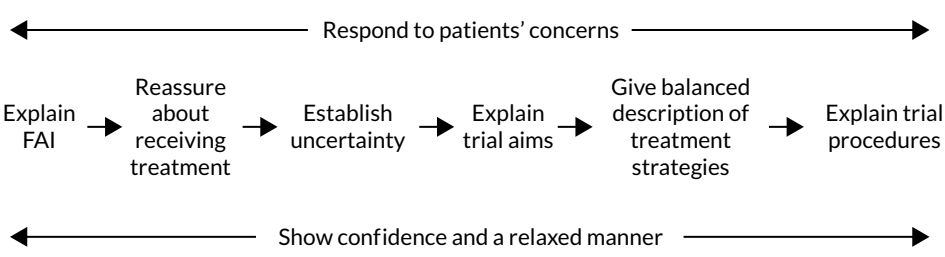

FIGURE 1 Six-step model for recruitment to the FASHIoN trial.

After sites started recruitment, the QRI team used various methods to describe recruitment as it happened. The QRI team contributed to monitoring and supporting recruitment by providing feedback on their findings to the chief investigator and TMG, which provided the basis for a plan of action to improve it.[71] These methods were:

- mapping eligibility and recruitment pathways
- interviewing clinicians and RAs responsible for recruitment
- analysing audio-recorded recruitment appointments.

The QRI methods were not necessarily employed sequentially. The ethnographic nature of the QRI meant that the research was moulded to fit the needs of the project and was completed when theoretical saturation was reached (i.e. new data collection did not materially add to the findings). Observation of investigator meetings was carried out informally as one member of the QRI team (AR) worked closely with the TMG.

Qualitative research data were collected at 20 participating sites that recruited patients for the RCT. Two sites were excluded from this report, as they had only started recruitment 2 months before the end of the trial. In the following sections, we will report the data sets, analytic approach and results of each of the three QRI components.

Mapping of eligibility and recruitment pathways

A comprehensive logging process of potential RCT participants through screening and eligibility was put in place to ensure compliance with the CONSORT checklist. These data were made available to the TMG and qualitative researcher (AR) on a monthly basis. This information was complemented with information from weekly trial co-ordination meetings. Trial staff often shared with the QRI team information obtained during their individual contact with participant sites recruiters, such RAs, PIs or R&D personnel.

We also obtained information about recruitment pathways from in-depth, semistructured, face-to-face and telephone interviews with site research staff. Soon after recruitment started at sites, we invited PIs and RAs recruiting patients to the FASHIoN trial to an interview. We targeted new staff at pilot sites and research teams at sites new to the trial. More details about these interviews are provided in *Interviews with clinicians and research associates responsible for recruitment*.

Aggregated data from these sources were used to develop site-specific flow charts of the most likely patient pathways. These pathways were assessed for their complexity and compliance with the protocol-planned patient pathway (*Figure 2*). We aimed at identifying variations between centres, finding steps where patients could be 'lost' to the RCT and, when possible, working with site research teams to modify the pathway to facilitate recruitment.

Findings

Patient pathways from eligibility to recruitment varied across participating sites, which was reflected in different numbers of patients screened, approached and consented to be trial participants. Differences between sites are expected in a pragmatic trial; however, these differences were relevant to trial recruitment success. Therefore, we decided to compare regular sites and sites that struggled to recruit. Struggling sites were defined as sites that had a recruitment rate (i.e. the number of eligible patients recruited per centre per month) smaller than the target rate of 0.5 patients recruited per month. *Table 4* highlights contrasting aspects of the recruitment pathway between the two site categories.

Patients were referred from other orthopaedic units and musculoskeletal triage systems. Most patients had a multitude of contacts with different professionals and very rarely came directly from general

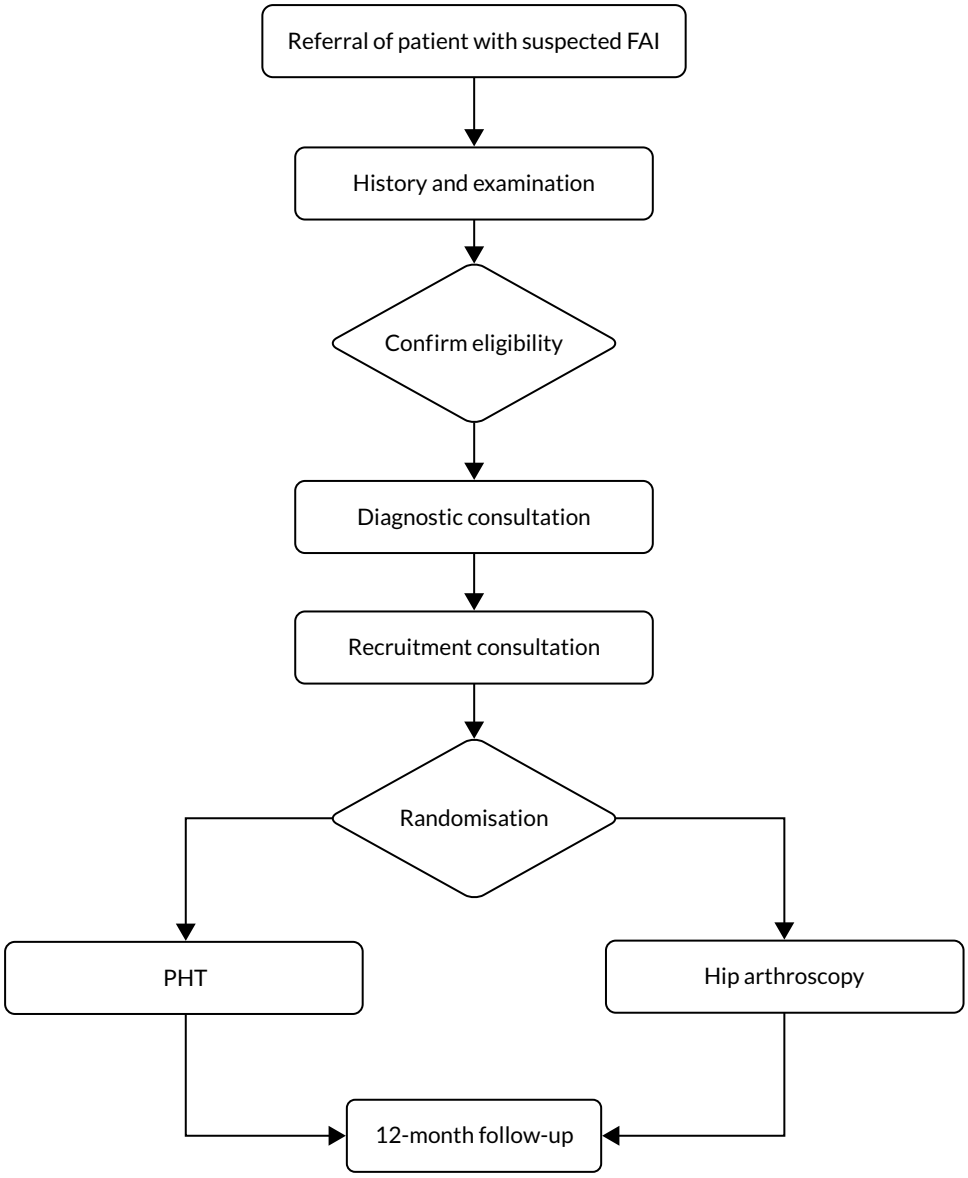

FIGURE 2 Recruitment pathway in accordance with the protocol: the FASHIoN trial.

TABLE 4 Contrast on recruitment pathway characteristics between regular and struggling sites

Site	Characteristic
Regular site	Accurate screening logs (e.g. databases included potential participants that need follow-up at a later date)
	Follow-up of patients who had gone for further tests and procedures
	Collaborative decision-making process for eligibility
	An 'active' RA helping clinics with eligibility, approach and follow-up
Struggling site	Multiple contacts with other clinicians before referral
	Complex cases
	Inconsistent screening logs (e.g. registering only patients who were eligible or all patients in clinics independently of diagnosis)
	No accurate follow-up (e.g. previous patients added as new in screening logs)
	Surgeon-only decision-making for eligibility
	A 'passive' RA who waits for surgeons' directions

practitioners (GPs). In fact, struggling sites reported receiving a number of 'complex cases'. These cases were generally referrals from other orthopaedic surgeons who had advised patients to have hip arthroscopy. This type of referral concerned recruiting surgeons, in particular, because patients had waited a long time to receive surgery, for example one PI said:

> *The patient's mind has already been made up by people they've seen before me and generally by the nature of the condition, they've often seen a lot of people before they get to my clinic.*
>
> *PI site 21*

Adding to long waiting times, often suspected FAI patients did not have the correct imaging at the first appointment with the consultant. It was not possible for orthopaedic surgeons to confirm patients' eligibility to participate in the FASHIoN trial and usually further tests had to be ordered. This meant that approaching patients about the trial had to be postponed until their diagnosis was confirmed. In addition, some patients had to be treated or, at least, examined for concurrent symptoms, as explained by one RA:

> *We have had a few [patients with] FAI but they have got trochanteric bursitis, or we have got ones with the back pain, so they first have to investigate that, and then they come back.*
>
> *RA site 8*

Although potential participants had been identified during screening and recorded on the screening log, some of these prospective participants were not then approached at follow-up clinics. The TMG published a list of patients waiting for FAI to be confirmed and asked RAs to find out their final diagnosis. This step in the recruitment pathway helped to identify a few eligible patients, among many others, who did not fulfil the eligibility criteria.

Other misunderstandings and errors in screening logs were made in the first 6 months of recruitment. For example, although a high-volume centre was registering every patient attending an orthopaedic clinic, independently of their diagnosis, other sites reported only patients who agreed to become FASHIoN trial participants. To avoid further errors, the screening logs were redesigned to facilitate a standard registration of eligible and approached patients.

In relation to the decision about who to approach, some regular sites' research teams collaborated in the decision process, whereas struggling sites relied on the recruiting surgeon's decision alone. The following quotations exemplified this contrast. The first quotation is from a site that recruited well, the second from one that was less successful:

> *So prior to the clinic on that Monday, I go through all the notes of the patients and have a look at their referral letters to see, because some of the referral letters, the GP or whoever else has referred them, may suggest that they suspect that there's an impingement. So if there are any of those, I flag that up to [the surgeon] and I see if they've had an MRI done.*
>
> *RA site 17*

> *[The surgeon] is quite happy to discuss all the patients at the beginning of the morning to make sure we've found the right ones, you know, [the surgeon] checks them all through.*
>
> *RA site 21*

Research associates in regular sites had an active role in detecting potential participants and confirming their eligibility with recruiting surgeons. During the induction, RAs were trained to identify potential patients based on the referral letters by the trial clinical research fellow (EJD). Surgeons and RAs would look at their clinic list together and decide who to approach. Teams took ownership of the trial and often talked in collective terms about their activities, as exemplified in the quotations above. These teams created a reliable recruitment system that was repeated consistently.

In contrast, recruiting surgeons at struggling sites usually had the responsibility to check patient eligibility and introduce the study to potential participants. Surgeons would then instruct RAs to contact the potential trial participant at a later date. RAs often contacted patients by telephone. Occasionally, RAs would be contacted on the same day and would be able to talk to the patient. Sites often did not have a reliable recruitment system or a settled recruiting team. The following quotations illustrate these difficulties:

> *What tends to happen is [recruiting surgeon] sees them in clinic, he has a chat with them. He then e-mails me and says 'I've seen Mr Smith, can you contact him? He is appropriate for the study'.*
>
> *RA site 3*

> *So he'll e-mail me . . . He'll introduce the study to the patients and he's got information sheets that he passes on then I then approach the patient by phone call or letter.*
>
> *RA site 14*

Research associates who become proficient and confident at identifying potential participants had a pivotal role in organising recruitment. Their actions reduced the impact of contacts with other professionals (e.g. registrars) who interfered in the recruitment path:

> *The registrars will discuss [potential participants] with [consultant surgeon] first and I always make sure they have. I never take that for granted, because [consultant surgeon] is who has to sign the actual form.*
>
> *RA site 10*

Some recruiting surgeons would ask RAs to be present while they talked to patients about the trial, whereas other surgeons would spend time talking to patients alone first and then ask if they would like to talk to the RA. We recorded reluctance from surgeons to share recruitment responsibilities, as illustrated in this quotation:

> *I'm struggling with this trial in that you have to stop at a point to hand over to the research nurse.*
>
> *PI site 11*

We observed that recruiting surgeons contributed to promote patient equipoise when they worked with RAs to have a separate consultation with patients. A RA from a site that recruited consistently said:

> *The surgeon presents the [interventions] both as equally beneficial to the patient.*
>
> *RA, site 12*

Finally, often RAs at regular sites embraced the use of the six-step model enthusiastically, whereas in struggling sites the model was perceived as less useful. This is a quotation from an RA in relation to the model:

> *And I don't read [the model] out word for word but it kind of makes sure you're doing things in the right order and with the right stresses and, and going the right way. So yes, I find [the model] quite useful.*
>
> *RA, site 2*

Interviewing clinicians and research associates responsible for recruitment

In-depth, semistructured, face-to-face and telephone interviews were conducted with PIs and RAs recruiting patients to the FASHIoN trial. Staff at new participating sites and those new staff at pilot

sites were invited to take part. Interviewees were encouraged to express their own views about the RCT and any recruitment challenges expected or experienced. The interview topic guide covered:

- personal views about the evidence supporting the trial and their equipoise
- the patient pathway from eligibility to recruitment
- how interviewees feel the protocol fits their clinical settings
- interviewees' views on recording consultations with patients
- any adjustments interviewees thought were needed to the trial procedures.

The recordings were transcribed and analysed thematically by Alba Realpe, using techniques of constant comparison and case study approaches. Themes were compared, looking for shared or disparate views among research team members. Coding was carried out using the qualitative data analysis software NVivo (QSR International, Warrington, UK). Detailed descriptive accounts of the themes and cases were produced. The initial coding was checked by other QRI researcher (MJ), with inconsistencies resolved by discussion. The cases were presented to the chief investigator and TMG, and were used to plan specific actions and support for participating sites.

Findings

Data interpretation focused on learning about recruitment difficulties that sites experienced, with the purpose of finding solutions in collaboration with the TMG. Reported difficulties coincided with those reported in past research,[40] which was used to classify findings in three axial themes: (1) logistic difficulties, (2) recruitment experience and skills and (3) engagement with the trial.

Logistic difficulties

Sites readily reported logistic issues that had an impact on their recruitment performance. This category is related to the detailed organisation and implementation of the recruitment process at the participating site. The most frequent issues in this category are reported as follows.

Infrequent scheduled clinics

Annual leave, academic breaks, different site locations and bank holidays had an effect on the number of patients available to surgeons because clinics were held on specific days of the week (e.g. Mondays). For example, one RA said that 'we've been struggling getting going because there's been holidays' (RA site 19). More struggling sites ($n = 6$) reported this issue than regular sites ($n = 2$).

Clinic cancellation impact on future recruitment

When clinics were cancelled, waiting lists became longer than expected and recruitment to the trial stopped. For example, in one site clinics were held without the knowledge of research support staff and in another site recruitment was postponed to stop clinics over-running.

Low staffing levels imposed pressures on principal investigators

Low staffing levels was a relevant issue for senior consultants who relied on registrars and junior doctors in teaching hospitals:

> *[The surgeon] has also had problems with not having registrars or fellows to help in the clinic.*
>
> *RA site 8*

Consequently, RA attendance to clinics became a key factor for recruitment success because they were able to take on research activities, such as screening logs and trial-specific paperwork.

Lack of young hip-only clinics

Finding eligible patients in generic orthopaedic clinics was difficult because clinics included revision surgery or other lower limb conditions. To overcome this limitation, site staff rescheduled new patients into young hip-only clinics. However, not all sites had systems that allowed such flexibility. Indeed, struggling sites had fewer young hip-only clinics than regular sites.

Lack of a private room to talk to potential participants

This issue was often reported as a major recruitment difficulty because, in accordance with the TMG recommendations and protocol, patients ideally should be approached soon after talking to their surgeon. Finding a private room to talk to patients had logistic implications for teams running busy clinics. For example, one RA described a situation in a clinic:

> *I had to hang around outside a room waiting for a patient to come out.*
>
> *RA site 21*

Another RA felt that she had to battle with colleagues and management until she was 'able to have a room to myself and talk to patients' (RA site 12).

Concerns with processes after trial consent

Site teams reported a few cases ($n = 3$) of patients deciding to opt out of the trial after randomisation. There were also difficulties with long waiting times for having the hip surgery and postoperative MRI.

Recruitment experience and skills

Recruitment experience and skills refers to the site teams' reported barriers to recruitment derived from their experience approaching patients to this trial, such as patient responses to the trial and how to respond to them. The main issues in this category were as follows.

Uneven levels of experience conducting randomised controlled trials in orthopaedics

Having experience conducting RCTs in orthopaedics helped teams to have recruitment success in this particular trial. Seven regular site teams and one struggling site team reported having carried out RCTs before. However, of the eight research-naive teams that took part, four achieved their recruiting targets.

Principal investigator's lack of knowledge of the non-surgical arm

Eight PIs reported having difficulties explaining PHT to patients. The PIs did not know the physiotherapy protocol and one surgeon expressed some doubts about offering this treatment:

> *We don't know what a normal physiotherapy would be for this condition.*
>
> *PI site 11*

This issue was relevant, as five of the eight PIs were at sites that struggled to recruit.

Strong patient preferences for surgery

Site teams reported the issue of patients preferring surgery. On the one hand, struggling sites found that patients were less inclined to take part in the trial because they had already had physiotherapy or were in physical occupations (e.g. police, fire fighter). It was reported that these patients thought that they required a more invasive treatment (e.g. surgery). For example, a recruiter explains:

> *We get quite a lot of dancers so I've seen one or two dancers who've come and they just want to get back to dancing, and they feel that surgery will just resolve it all.*
>
> *RA site 14*

On the other hand, regular site teams cited patients preferring not to be in the trial because of specific personal circumstances (e.g. moving abroad) or information bias from referral surgeons. Although the issue of having previous physiotherapy was also brought up in these sites, it was often successfully challenged.

Lack of opportunities to practise recruitment skills

Recruiters reported requiring practise to develop an effective approach, but lack of, or only sporadic, potential participants made this practise difficult to maintain.

Having to consent to audio-record consultations

Recruiters mentioned being uncomfortable about asking for consent to record recruitment consultations. In part, this was because of the extra logistics involved, such as having a working audio-recorder ready, but mainly recruiters felt uncomfortable for approaching potential trial participants before they discussed their diagnosis with the treating surgeon.

Having to explain randomisation to patients

Recruiters thought that patients often found randomisation unacceptable. For some RAs, the problem was that patients preferred not to have their treatment selected at random. For other RAs, the difficulty was based on misunderstandings:

> *[After explaining about randomisation] the next following question is, 'so which do I get to pick?' [laughs].*
>
> *RA site 12*

Engagement with the trial

Engagement with the TMG set apart regular and struggling sites. Although most regular sites were approached to take part in the FASHIoN trial and, therefore, communication between the main site research team and site teams was established early on, other site teams submitted a request through the National Institute for Health Research portfolio and, therefore, staff at struggling sites in this group expected to receive most of the support from their local R&D group. As a consequence, their communication with the main site research team was scarce.

Overall, recruiters expressed positive views of the FASHIoN trial, independent of how well their site team recruited, as illustrated by the following quotation:

> *I've found FASHIoN, you know, a particularly nice project to work on. It seems to be very well set up and organised and a very supportive team, which has been really good.*
>
> *RA site 21*

Recruiters also remarked on the type of patients and their reactions to the trial:

> *It's a really interesting patient group being, sort of, bit younger to what we normally look at with hips because I work on another hip trial which is mainly looking at the hip fractures . . . this has been lovely to be able to chat to a younger group of patients, sort of who are a similar age to myself as well which is always interesting.*
>
> *RA site 16*

Recruiters noticed patients' positive reaction to information-sharing about their condition:

> *Because for some of them it's the first time they would have had information, printed information in front of them, that really tells them about the condition. So they appreciate that.*
>
> *RA site 20*

Similarly, recruiters reported patients being pleased with having an extra consultation with the research nurse and an opportunity to ask further questions:

> *They know that we're not rushing them; that they can ask anything.*
>
> *RA site 2*

> *Yeah, more in the men than the women and sort of then explaining why we leave it to the research nurses to discuss the trials rather than the surgeon. And they like that and they think that is a good way of doing things. I haven't had any sort of bad comments about me coming in to discuss the trial and not [recruiting surgeon] and I haven't had any comments made towards them saying we don't know which works best.*
>
> *RA site 16*

Positive patient reactions to the trial contributed to easing recruiters' concerns about offering this trial to patients, especially in relation to having physiotherapy instead of surgery. Clinical equipoise is discussed below.

Views on equipoise

Most recruiting surgeons expressed their agreement about the lack of strong scientific evidence in favour or against hip arthroscopy. Surgeons supported the conduct of a RCT in this area.

Being surgeons, most recruiters preferred surgical intervention for FAI syndrome, but reported that they were able to 'suspend' their clinical judgement. Some recruiters seemed rather comfortable offering the trial to patients:

> *I feel [FAI] patients don't get enough physiotherapy.*
>
> *PI site 20*

> *I've got no qualms about offering [patients] [PHT] at the start of the study.*
>
> *PI site 21*

Other recruiters (two PIs and eight RAs) expressed concerns because they believed that those in the surgical arm were worse off:

> *If the physio[therapy] didn't work you've always got the option of the arthroscopy, but then if you opt for the arthroscopy, OK they can say there's still the physio afterwards but then you've put yourself through all that trauma.*
>
> *RA site 11*

Finally, other recruiters assumed a laissez-faire attitude to patient trial participation decisions:

> *I mean basically I have got my own electronic [list], which has got their phone numbers and address and everything on it and then as I work through they either become consented, which one lady has, or they drop out as not interested.*
>
> *RA site 3*

Different levels of equipoise were observed at regular and struggling sites. Most revealing was the lack of surgeon engagement in struggling sites:

> *I feel the consultants probably need to be more on board with it and sell it a bit more. So that's been challenging because we're new to research . . . I'm not usually a very pushy person but I feel that I have to do that to the patient as well as a consultant, in a nice way, you know.*
>
> *RA site 14*

Analysing audio-recorded recruitment appointments

The third and last component of the QRI (i.e. analysing the audio-recordings of recruitment appointments) had the following objectives:

- to identify communication practices that encourage or hinder patient participation into the trial
- to use this information to develop training materials and support for research teams' recruitment efforts.

During the pilot, we hypothesised that using a six-step model of recruitment encouraged participation in this trial. Therefore, the six-step model was the benchmark for the analysis of communication practices in the full trial. We assessed whether or not recruiters used the six-step on their recruitment consultations and, if so, whether or not this use influenced conversion of patients into trial participants.

Procedure

Participating sites were asked to produce as many recordings as possible of two pivotal appointments in the recruitment to this trial. The first appointment to be recorded, named the 'diagnostic consultation', was the appointment when patients were told about their diagnosis. We advised recruiting surgeons to present the trial using the first four steps of the recruitment model (i.e. explain the condition, reassure about receiving treatment, introduce uncertainty and explain study purpose), to answer patient questions and to invite patients to talk to RAs about the trial.

The second appointment was the 'recruitment consultation', defined as the appointment at which randomisation was discussed. The training of RAs emphasised using the six-step model to structure information given to patients about the trial during the recruitment appointment.

The TMG explained and promoted the QRI at site initiation visits. All materials for recording consultations (i.e. patient information sheets, consent forms for audio-recording, digital audio recorders and instructions for the operation of the recorder and the naming and transferring of data to the QRI team) were given to a main contact within the site team, generally the RA assigned to the trial.

Prior to their consultation with the surgeon, RAs gave patients who could potentially become trial participants at clinics the patient information sheet for the audio-recording of consultations to read. If patients agreed to become trial participants, they were asked to sign a consent form. RAs then proceeded to record the following appointments as per protocol. The recordings were then anonymised and sent securely to the QRI researcher for analysis.

A coding manual was developed and applied directly to the audio-recordings (not transcripts) using NVivo software. After the analysis, the QRI researchers decided what confidential feedback would be given to the recruiters. Teams were assured that the feedback to them was going to be confidential and positive (not critical). Other issues were fed back to the RCT chief investigator/TMG, or were used anonymously in training programmes.

Analytic approach

The sample was purposively selected to include patients who agreed and did not agree to take part in the FASHIoN trial. Good-quality recordings of recruitment consultations (and diagnostic consultations, when available) were analysed with a modified version of the Quanti-Qualitative Appointment Timing method that has been pioneered in previous studies.[75]

Using the Quanti-Qualitative Appointment Timing approach, we determined the percentage of time recruiters spent in each of the six steps of the recruitment model and the sequence in which they were used by recording when a recruiter used a step for the first time. We then evaluated appointment content for unbalances and untoward emphases that may upset patient equipoise using focused conversation analysis. In addition, patient questions, concerns and preferences were coded and frequencies tabulated.

Two coders tested the reliability of the coding system (i.e. inter-rater reliability). Consultations of six individual patients were coded and Cohen's kappas calculated. After reliability checks were satisfactory, we applied the coding to the remaining consultations.

Findings

We received 153 audio-recordings corresponding to 129 individual patients from 11 sites between September 2014 and March 2016. *Table 5* contains the characteristics of the audio-recordings, patients and clinicians in this sample. Patient and recruiter characteristics did not differ from those of the trial participants as a whole.

Recordings selected for analysis comprised a combination of patients who agreed to take part in the trial ($n = 44$) and those who declined ($n = 29$). The average length of recruitment consultations was 16 minutes 50 seconds and the average length of diagnostic consultation was 7 minutes 57 seconds. The minimum number of recordings per site was two and the maximum 22. Other recordings were excluded because they were incomplete ($n = 17$), patients in the recordings were not eligible ($n = 12$), patient diagnosis was uncertain ($n = 8$) or the recording included more than one recruiter ($n = 9$).

Coding reliability

The QRI researcher and an independent qualitative researcher achieved substantial agreement ($\kappa = 0.67$) in the coding of a subsample of six consultations. Both the QRI researcher and the independent qualitative reached almost perfect agreement when identifying statements explaining details of hip arthroscopy, PHT and randomisation ($\kappa > 0.8$). Coders disagreed more often ($\kappa < 0.4$) when identifying statements of reassurance (step 2) and uncertainty (step 3), in part, because reassurance was seldom used and uncertainty often appeared paired with study purpose (step 4).

Diagnostic consultations

We received 34 diagnostic consultations and in 22 of these consultations patients became trial participants. The remaining 12 participants declined participation. We observed two different approaches

TABLE 5 Characteristics of the audio-recording sample

Audio-recording characteristic	Total
Collected, *n*	153
Selected for analysis, *n*	107
Excluded, *n*	46
Diagnostic and recruitment consultation pairs, *n*	34
Recruitment consultation by surgeon, *n*	13
Recruitment consultation by RA, *n*	26
Individual patients, *n*	78
Males, *n*	42
Females, *n*	36
Average age (years)	34.8
Individual recruiters, *n*	
RAs (nursing or physiotherapy background)	18
Orthopaedic surgeons	12
Average number of recordings submitted	3

to diagnostic consultations. Some surgeons spent time going through trial information with patients, whereas others made a brief intervention and handed over the potential participant to the RAs.

Figure 3 shows the distribution of the time spent on different elements of the consultation, comparing consultations in which the patient agreed to participate with those in which they did not. Recruiting surgeons spent more time framing the decision using the first four steps of the model in trial participant consultations than in non-participant consultations. This was also the case in relation to answering patient questions and providing information about PHT, hip arthroscopy and RCT procedures. These recruiters spent less time dealing with patient concerns and preferences than their colleagues in non-participant consultations.

In relation to the sequence in which information was given, we observed that surgeons used the first four steps before explaining study procedures in 16 consultations and in 10 of these of consultations patients became trial participants. When the sequence was reversed, four out of five patients took part in the study. Surgeons did not mention randomisation in 13 consultations and in eight of these consultations patients became trial participants.

These results suggested that surgeons managed to convert patients into participants more often when they framed the decision of trial participation, answered patient questions about their medical condition and treatment alternatives, and did not go into much detail about study procedures or randomisation.

Recruitment consultations

Our results indicate that the majority of recruiters used the model to structure their consultations, as per training. On average, 72.8% (SD 16.5%) of the consultation time was spent introducing information based on the six-step model. The remaining time was spent taking medical history, giving instructions and chit-chat.

Figure 4 shows time distributions of recruitment consultations. More time was spent talking about study procedures and the non-surgical arm in trial participant consultations than in non-participant consultations. Furthermore, patients appeared to have fewer questions, concerns and preferences in the former than in the latter.

Most recruiters ($n = 47$, 64%) used the information delivery sequence suggested by the model. Recruiters framed patient decisions using the first four steps of the model and then proceeded to

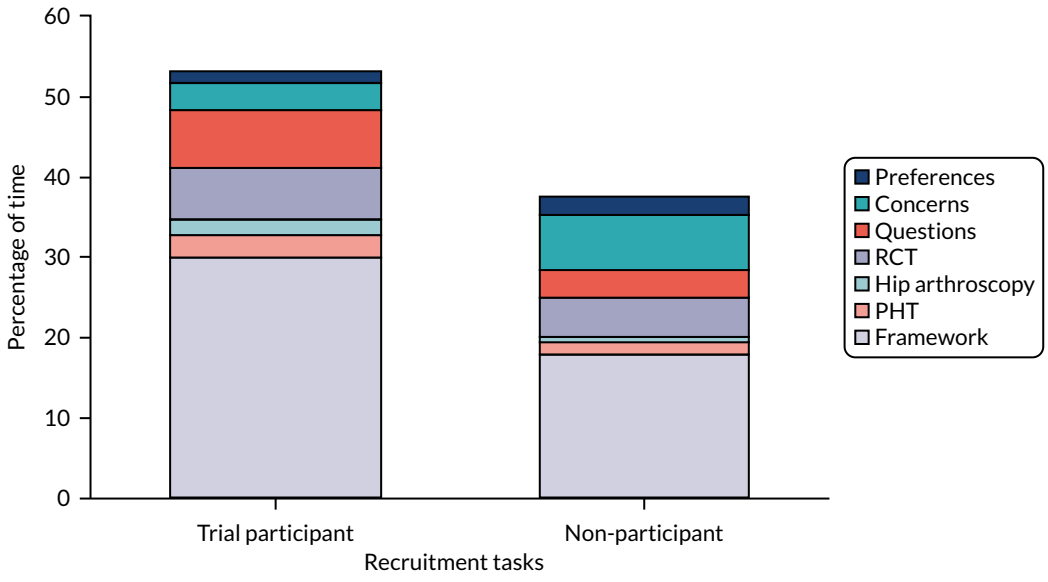

FIGURE 3 Percentage of time dedicated to specific recruitment tasks in diagnostic consultations.

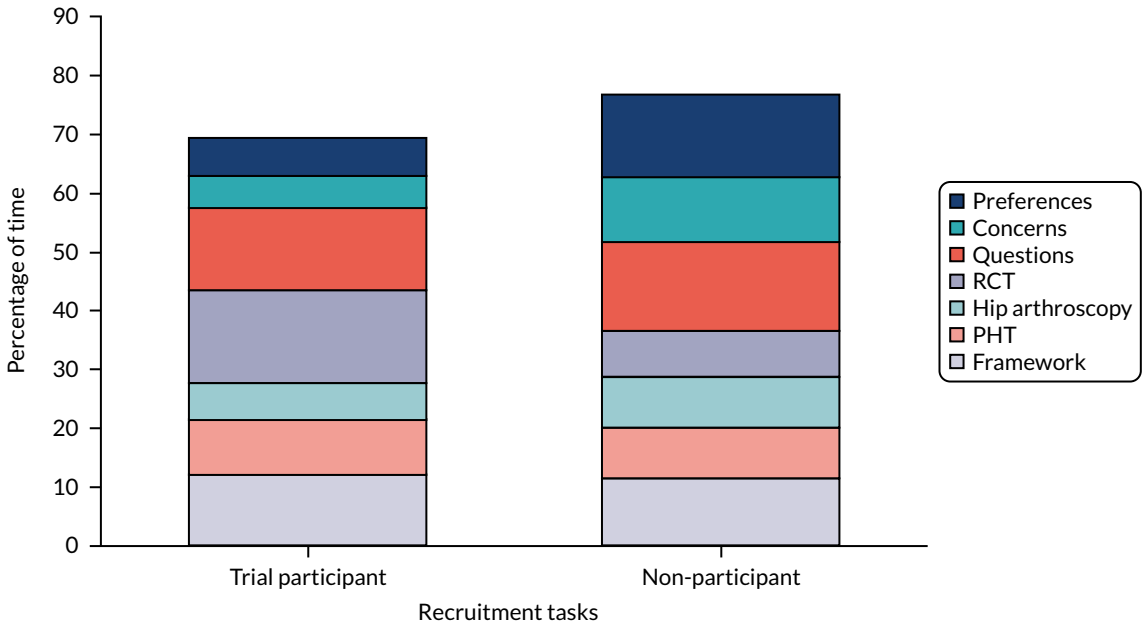

FIGURE 4 Percentage of time dedicated to specific recruitment tasks in recruitment consultations.

introduce information about randomisation. Recruiters did not use this framework in 20 cases (27%). However, independent of the chosen sequence, 50% of approached patients became trial participants.

In relation to the content of recruitment consultations, we observed little variation on topics because recruiters were provided with extensive training. The content of consultations became highly standardised in a script available to recruiters in cue cards (see *Training site teams on recruitment strategies and trial-specific information*).

Our observations and recruiters' reports indicated that recruitment to this trial depended on two pivotal aspects of recruitment: (1) recruiters needed to make an argument in favour of PHT and (2) recruiters needed to describe randomisation in a way that was acceptable to potential participants.

Making an argument in favour of PHT was especially challenging when patients have had previous hip-specific physiotherapy. Recruiters succeeded at promoting patient equipoise when they knew details about PHT and were equipped to answer patient questions about this treatment arm. Recruiters used their knowledge to dispel misconceptions or calibrate treatment expectations by given details about how a treatment may affect the person at an individual level.

The following extract is an example of how this strategy worked. The recruiter offers an interpretation of patient preference and confronts this assumption based on her own clinical experience, which the patient accepts:

> Patient: *Yeah and it's funny maybe I don't get that when I – and I find like picking up my son if I go like that hhh I don't have any power, I don't have any – is that sort of thing*
>
> Recruiter: *[Inaudible]*
>
> Patient: *But I think . . .*
>
> Recruiter: *The thing is, if you just must think, because if you think about the surgery as mechanical . . . just taking the bump away and then it's away . . . but I also work in the clinic follow-up of people post surgery*

Patient: *Hmmm*

Recruiter: *And I did find that some of the high-level sports people it's taking us a year to a year and a half to actually get them – and some people you don't, some people are always off, so you do get worse off so ehm . . . after surgery it's not all just straightforward*

Patient: *No, no, I understand.*

Contrast between previous physiotherapy and the new PHT arm could not always be achieved, either because recruiters used statements that were too general or irrelevant to patient needs, or simply because they did not know how different these approaches really were. The following extract exemplifies this type of exchange. The patient declares that he has already had physiotherapy and the recruiter attempts an open question but changes it for a closed one. The patient rejects the assumption and emphasises the difference. The recruiter moves to explain general aspects of PHT, but the patient rejects this. The recruiter persists but gives up at the end:

Patient: *I[ve already said] I had months of physio already though*

Recruiter: *Ahh yeah What kind of phys[io] is that through your GP?*

Patient: *No it was through the army*

Recruiter: *OK*

Patient: *Private physio*

Recruiter: *Right ahh . . . So what the physio is doing ahh is . . . the physio is a personalised hip therapy programme so you'd come to the hospital and see Mr [surgeon]'s specialist physio who deals with just hips, nothing else ehm which is where you get the personalised structure from ahh and what she would do with you is work with you to build up your muscles ehm and your hip [flexes]*

Patient: *I've already been doing [that]*

Recruiter: *And everything around . . . yeah ehm look at how ehm where your pelvis is positioned? So if you tilt your pelvis slightly forward, slightly back to get you in a good postural positioning [laughs] I'm preaching to a convert here, ain't I?*

Describing randomisation in a way that was acceptable to patients often challenged recruiters' equipoise. At times, conversations became awkward, hindering recruitment. The following extract illustrates this effect:

Patient: *I'd still do your study but I go the surgical route*

Recruiter: *That's a – that's another proble(h)m ehmm . . . to make it a fair test ahh . . . we . . . randomly allocated . . . your . . . option . . . so I don't get a say in what you get, you don't get a say and Mr [surgeon] doesn't get a say*

Patient: *[Sniggers]*

Recruiter: *So leave it to chance of which option you'd be given*

Patient: *I can't do that because I want to go back*

Recruiter: *I know*

Patient: *I'm in [timescale]*

Recruiter: *Have they said what sort of, what sort of*

Patient: *6 months to a year from when I get my discharge papers*

Recruiter: *That's your window of getting back in?*

Patient: *No that's how long I've gotta wait 6 months to a year*

Recruiter: *OK*

Patient: *Before I can reapply*

Recruiter: *OK*

Patient: *So I want to get my fitness back.*

Laughter in the patient response can be interpreted as responding to the awkward discussion about the surgeon not having a say, which the recruiter framed as 'another problem'. The patient continues to be concerned about the timescale of their treatment and uses this reason to opt out of the trial.

Finally, we noticed that step 2 of the model (i.e. reassurance about receiving treatment) was seldom used by recruiters. Only 23 of the 73 recordings contained reassuring-type statements and most of the patients from these recordings became participants (74%). Recruiters expressed concerns about using reassuring-type statements, as they may have been construed as undue influence or coercion. Nevertheless, it can be argued these statements were ethically valid because the FASHIoN trial was a superiority trial and, therefore, it was assumed that both treatments were effective. An example of a reassuring statement is as follows:

> *[Surgeons] know that both [treatments] work, treatment, trial or whatever, you're going to get treatment anyway, so physio and surgery, they both work.*
>
> *RA site 4*

Patient questions, concerns and preferences

Box 1 shows a sample of the list of common patient questions, expressions of concern and preferences that we collected during our analysis. Patient questions were more often recorded in trial participant consultations, whereas there were more expressions of concerns and preferences in non-participant consultations. This trend was expected, as patients in the latter group may not have been in equipoise.

Our observations of the recruitment process as it happened informed decisions about what support and training the QRI team and TMG could offer to site teams. These activities are described below.

Action plans to promote informed consent and improve recruitment

The QRI team worked closely with the FASHIoN team, creating action plans as soon as information from Phase I was available. The plans were implemented by the trial team and the QRI researcher assigned to the trial. This method is consistent with the QRI described by Donovan *et al.*[71]

BOX 1 Most common patient questions, expressions of concern and preferences

Topic	
Patient questions	
	How did I get FAI?
	Could it get much worse if left untreated?
	How long does it take to recover from hip arthroscopy?
	How many times would I have to come here [for PHT]?
	How does treatment get decided?
Patient concerns	
	I'm confused, the other doctor showed me a tear.
	I'm just in absolute agony at all times.
	If it is my abnormal hip shape, what difference physio is going to make?
	I don't like the idea of the computer choosing which way.
	HR is working to possibly getting me back to work because I don't get sick pay.
Patient preferences	
	I'm intrigued by both [treatments] really.
	I need to be in control of this [decision].
	I'm sick of having [physio]therapy.
	Physiotherapy is more suitable for me right now.

HR, human resources.

The results of Phase I indicated that sites that recruited well and those that struggled confronted similar challenges and, therefore, the trial team sought to standardise procedures as much as possible. Action plans focused on the following three objectives:

1. improving screening of eligible patients
2. facilitating recruitment site teams' participation and engagement
3. training site teams on recruitment strategies and trial-specific information.

Improving screening of eligible patients

A simplified screening form was introduced to correct screening misunderstandings and to obtain accurate estimates of patient recruitment. RAs received detailed instructions on how to fill out the new screening logs.

Research associates were asked to submit screening data and upcoming recruitment clinic dates on monthly basis, including whether or not a RA would be available to attend clinics. This information was reported during the monthly TMG meetings.

Reports to the TMG included an approach percentage and a conversion percentage for each site. The approach percentage was the percentage of eligible patients who had been asked to take part in the trial. The conversion percentage was based on the number of approached patients who became trial participants. These two percentages allowed the trial team to identify where potential problems in the flow of patients may be. For example, two sites recruited 0.6 patients per month; however, the sites

differed on their approach and conversion percentages. One site had a low approach percentage because patients travelled from Ireland to receive treatment and, therefore, these patients were ineligible to participate in the trial. The other site had a nearly 100% approach, but it did not convert patients to participants. There was not much that could be done with the composition of clinics in the first site, but the second team was offered further training on talking to patients about the trial.

The majority of participating site teams responded positively to these changes and RAs developed their own systems to report their recruitment numbers regularly. Screened patients almost doubled between September and January ($n = 352$) and the following 4 months after these changes were implemented ($n = 681$). The number of approaches and recruitment conversions increased slightly from 27 to 30 at the same sites.

Facilitating recruiting sites' participation and engagement

Information collected through interviews and screening logs for each site was organised into cases. Each case detailed team structure and number of patients screened, eligible, approached and recruited, as well as a description of any particular difficulties at logistic, engagement or skill level. Cases were discussed with the chief investigator and TMG in weekly meetings. A summary was presented and strategies to address particular issues discussed during the TMG monthly meetings.

Logistics/organisational difficulties

- Contact R&D group to guarantee time allocation for a research assistant to attend clinics regularly.
- Request screening logs and clinic dates monthly from sites through an Microsoft Excel® datasheet (Microsoft Corporation, Redmond, WA, USA).
- Provide further training on eligibility criteria.
- Alert PIs and other management personnel about delays in setting up a site.
- Deploy clinical fellows to cover clinics when RAs are not available.

Engagement with the trial

- Regular contact between trial co-ordinator and RAs.
- Regular telephone contact with PIs led by the clinical research fellow and the chief investigator.
- Monthly e-mail newsletters with recruitment rates and other news about the trial.
- Token incentives for successful recruiters, such as chocolate boxes and coffee vouchers.
- Branded stationery with trial logo [e.g. water bottles, pens, Post-it® slips (3M, Saint Paul, MN, USA) and mugs].

Generic and trial-specific recruitment skill level was an important aspect that required optimisation across sites. Improving recruiters' skills became a main target of the recruitment intervention, as explained in the next section.

Training site teams on recruitment strategies and trial-specific information

A comprehensive training programme was designed to support site teams in optimising their recruitment opportunities. Different activities were organised from the start to the end of the recruitment period. These activities responded to observations of common barriers and good practice across sites. A list of activities in chronological order is presented below.

Recruiters' workshop

At the beginning of the full trial, a half-day training event was offered to PIs and RAs from the 13 sites that were opened to recruit. The workshop aim was to equip site teams with knowledge and techniques that they could adapt to recruitment processes at their sites. The CI and trial team presented key aspects of conducting the trial, including a detailed description of the protocol, eligibility criteria, treatment specifics and study procedures. The QRI team taught the six-step model and illustrated how to deal with

common issues using case examples. Research teams had the opportunity to ask questions and discuss issues raised. Trial teams received the presentation materials and a manual that contained examples of good recruitment practice collected during the pilot trial.

Six-step model manual

A document explaining the six-step model for recruitment to the FASHIoN trial was distributed with the study file. The document contained a description of each step and provided examples extracted from the pilot recordings modelling good practice. The manual was an abbreviated version of the published article that RAs could consult for easy recall.[28]

Training the trainer

The clinical research fellow of the study (EJD), who was an orthopaedic surgeon in training, was responsible for delivering RA training on this specific trial. The QRI team worked closely with the clinical fellow, who received specific and intensive training at the beginning of the trial. His recruitment consultations were recorded and analysed, and feedback was discussed at these early stages. The clinical fellow also shadowed the chief investigator when approaching potential participants at clinics in the main site. The clinical fellow became an accomplished recruiter and was involved in all training events that were conducted during the full trial. He offered support through telephone and e-mail contact to RAs at participating sites.

One-to-one training

The clinical research fellow met in person with RAs at either the first site recruitment clinic or soon after. The purpose of this meeting was to discuss the recruitment strategy and build confidence in approaching patients. RAs had the opportunity to shadow the trainer or receive instant feedback from his observations. The clinical fellow and RA would discuss the strengths and weakness of the approach and further training contacts were planned, if required. When a face-to-face meeting could not be arranged, the clinical research fellow offered to role play over the telephone before the RA started recruitment.

Feedback on audio-recordings

Research associates who submitted recordings received individual written feedback from the QRI researcher. The feedback focused on issues related to phrases or vocabulary that could hinder recruitment. Discussions between RAs and researchers were positive, building on strengths, addressing misunderstanding and avoiding criticisms. This feedback offer was optional and not every RA received it.

Teleconferences

Two 1-hour teleconferences with RAs were conducted at the mid-point in the recruitment period. The calls aimed at increasing awareness of common recruitment issues and problem-solving by sharing experiences with each other. In the first teleconference, common patient questions and preference statements found on the QRI analysis of audio-recordings were used to facilitate discussion. The second teleconference focused on increasing RAs' knowledge of the trial treatments and, therefore, their ability to answer questions. Most of the RAs attended these teleconferences.

Teleconference summary leaflet

After the first teleconference, a guide was distributed to sites, which contained the most common patient questions, concerns and preference statements and suggestions to address them.

Newsletter supplement

A supplement to the newsletter, containing a summary of the main characteristics of the trial treatments, was distributed to teams following the second teleconference. The content was created and checked by the clinical team running the trial.

Note cards

Pocket-sized note cards containing key trial information messages organised according to the six-step model of recruitment were created. These cards were the result of the extensive analysis of recruitment consultations and were introduced as a memory aid for RAs. The note cards were distributed in the last few months of recruitment.

Evaluation of the qualitative recruitment intervention

The evaluation of the QRI comprised two data sets. The first data set was the overall trajectory of recruitment rates after action plans from the QRI were implemented. The second data set was the results of a survey of the RAs who participated in recruiter training activities. The survey asked RAs what work well in the trial and what could have been improved for future trials.

Recruitment rates overview

The FASHIoN RCT aimed to recruit 344 participants. Recruitment was planned to take place across 25 centres over a 20-month period. Centres would be open and recruiting 6 months after recruitment started. Forty-two patients had already been recruited in the internal pilot. The main RCT, therefore, needed to recruit an additional 302 patients.

Recruitment targets were set, assuming centres would comply with this schedule. *Figure 5* shows the original recruitment target line. However, there were considerable delays in opening centres, which had an impact on recruitment targets. An amended recruitment target line was estimated based on the actual numbers of centres open per month for the main trial. The recruitment target of 302 patients was achieved in 22 months and included 23 centres.

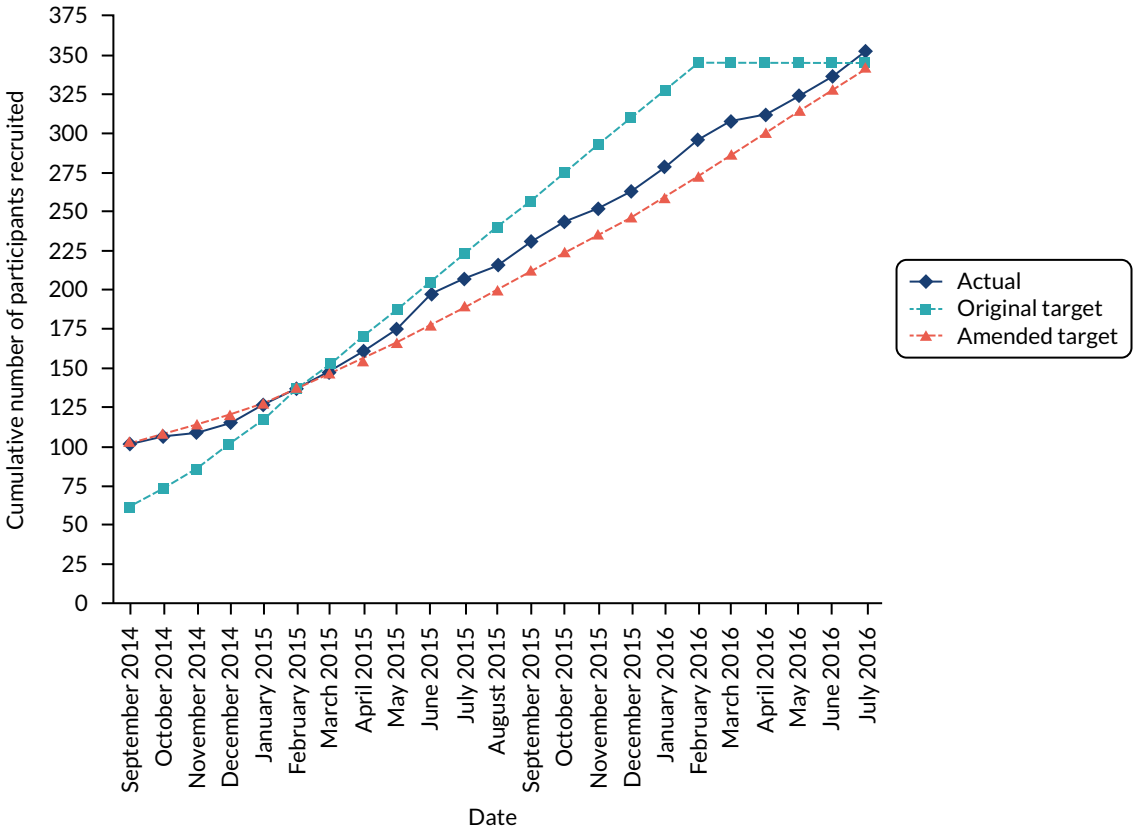

FIGURE 5 Target vs. actual cumulative recruitment: the FASHIoN trial.

Recruitment figures roughly followed the amended target line until March 2015, after which the actual recruitment figures started to exceed the amended target. Recruitment rates steadily remained above the amended target for the remainder of the recruitment period.

Research associates' survey on recruiter training activities

We conducted an online survey of FASHIoN trial RAs at the end of the recruitment period. The main aim of this survey was to gather views of a diverse group of recruiters about the strengths and weakness of recruitment training and trial conduct. We also sought advice about how to improve the design of future orthopaedic trials.

Procedure

We sent an invitation with a link to an online survey to the e-mail addresses of all RAs in the FASHIoN site delegation logs. Questions focused on three aspects of the FASHIoN trial:

1. recruitment training activities
2. study procedures (e.g. trial manager visits and attending clinics)
3. study documentation (e.g. trial file, patient information sheet and CRFs).

Research associates scored each trial aspect for its usefulness or quality on a five-point Likert scale. RAs were also asked to comment on what they would keep or remove from the FASHIoN trial activities. RAs compared the FASHIoN trial with other surgical and orthopaedic trials that they were working on and, finally, they provided details of role and experience. We sent the questionnaire 4 weeks after the recruitment period had finished. The survey ran for 6 weeks and two reminders were sent to those who had not replied.

Answers were aggregated and presented in tables organised by the online platform. A summary of the main findings is presented below.

Findings

We sent the invitation to 38 individual e-mails and received replies from 27 RAs: the response rate was 71%. Non-respondents were mainly staff who had a brief involvement with the trial, had covered annual leave, were RA managers or had left their role. We are confident that those who replied were directly involved in talking to potential participants in this trial.

The majority of RAs had a clinical background (only three RAs did not). There were 18 nurses and five physiotherapists. Experience as a recruiter to research studies varied. Forty-eight per cent ($n = 13$) of recruiters had < 2 years in the role, whereas others had been recruiting for up to 10 years. Seven of the most experienced recruiters were senior research nurses and managed other research nurses. More than half (66%) of recruiters had recruited for other orthopaedic trials and spent most of their working time on this role. RAs were involved with a range of studies (from 2 to > 20). Eight (29%) recruiters were working on the FASHIoN trial exclusively.

Recruitment training activities

We asked recruiters how useful they found each of the seven training activities described in Phase II. We obtained many 'not applicable' responses recorded in activities that happened once. The results are as follows.

One-to-one training

One-to-one training refers to meetings between the clinical research fellow and RAs at the first recruitment visit. Seventy-seven per cent of RAs rated this training as overwhelmingly useful and only six RAs said that it was not applicable. In the comments, one RA wrote:

> *It is good to receive one-to-one training. It is also good to hear from a clinician rather than someone with an admin background, as they understand the interventions more.*

Six-step model manual

The six-step model manual provided details of the six-step model to good recruitment practices. Eighty-one per cent of RAs found the manual useful or very useful, three RAs said that it was only moderately useful and two RAs said that it was not applicable.

Recruiters' workshop

The recruiters' workshop was a half-day training event that was offered at the beginning of the recruitment period. Forty-seven per cent of RAs considered the workshop useful, but 53% of RAs said that it was not applicable.

Feedback on audio-recordings

Individual feedback was offered to RAs who submitted audio-recordings. Thirty-eight per cent of RAs did not receive this type of feedback. Views on how useful this activity was varied from not useful at all (7%) to extremely useful (19%).

Teleconferences

Two teleconferences were conducted at the mid-point of the recruitment period. The teleconferences were considered as not applicable to nine (35%) RAs in this sample. Eleven (44%) RAs found the teleconferences very or extremely useful and six (22%) RAs did not find them useful.

Teleconference summary leaflet

A summary leaflet of the first conference was distributed to sites. RA views of the leaflet mirrored their views of the two teleconferences (see *Teleconferences*). Twelve (46%) RAs thought that the leaflet was very or extremely useful, seven RAs (25%) thought that the leaflet was not useful and seven RAs (25%) marked it as not applicable.

Note cards

Note cards, containing key trial information, were introduced in the last few months of the trial as a result of extensive analysis of audio-recordings. Consequently, the note cards were not applicable to five (18%) RAs. All RAs who received the note cards found the cards useful, with 70% of RAs saying that they found the cards very or extremely useful and three (11%) RAs saying that they found the cards moderately useful.

Study procedures

In relation to how difficult or easy the study procedures were, the survey covered all aspects, from setting up the trial to follow-up procedures. Procedures catalogued as easy or neutral included communicating with the TMG, working with the local PI, completing CRFs and obtaining clinical data about participants. A small number of RAs reported difficulty in setting up the study, attending clinics, identifying eligible patients, approaching eligible patients and obtaining informed consent.

Two aspects of the study procedures that were rated as difficult by RAs were (1) having a separate recruitment consultation after the diagnostic consultation ($n = 7$, 28%) and (2) recording consultations ($n = 7$, 28%). Notably, the RAs said that these difficulties differed from other trials in which they had been involved. However, overall, RAs were satisfied with the study procedures.

Research associates were very satisfied with the trial management support, specifically in relation to dealing with treatment-specific queries, general trial queries and telephone and e-mail contact with the trial team. A RA made the following comment:

> *The trial management team were excellent in this study. Easily accessible and very helpful and professional.*

Study documentation

Research associates' ratings of study documentation (including information about FAI and treatments, the trial site file, the patient information sheet, screening logs, CRFs, the trial manual and the newsletter) ranged from good to excellent in all questions. A comment from one RA reads:

> *Having worked on many studies now, I appreciate how hard is to design and produce such high quality of documentation.*

When we asked RAs to compare FASHIoN trial procedures and documentation with that of other trials they had been working on, ratings ranged from good to excellent. We noticed a few not applicable responses from RAs who had not worked in other trials.

Overall, RAs reported satisfaction with study procedures and documentation, as well as with the range of recruitment training activities. The trial was well resourced in terms of staff and budget, and this allowed consistent communication between the trial and site teams and resulted in highly professional documentation.

Emphasis on RAs talking to patients in a separate recruitment appointment and the use of a recruiter training programme made the FASHIoN trial somewhat different from other orthopaedic trials. It is not surprising that RAs found these extra activities more challenging than other common trial procedures. For example, there were suggestions to remove recordings from future trials, as RAs found recordings awkward and feedback was inconsistent and may have felt critical at times. However, RAs appreciated the note cards, which could not have been created without data from these recordings. Another strength of our approach was having a variety of activities for recruiting staff who usually have a high turnover. This meant that recruiters were well supported, as evidenced in their feedback.

Discussion and conclusions

We reported various processes aimed at optimising recruitment to the FASHIoN trial. The first phase of the recruitment intervention provided an understanding of the reasons for recruitment rate differences between sites that recruited well and sites that struggled. Equipped with this knowledge, the TMG and QRI teams modified or created processes to support sites in improving or maintaining their recruitment rates (e.g. monthly monitoring of screening logs and extensive RA training). Recruitment rates were maintained and the recruitment target sample was achieved, albeit a few months later than estimated. In the remainder of this discussion, we will discuss some limitations of these findings, then we will consider the relationship between this work and prior QRIs.

There are two limiting conditions to the conclusions that we can draw from our findings. First, the recruitment intervention was applied to only one specific RCT dealing with one specific patient group. Therefore, action plans may be applicable to this trial only, for example whether or not the six-step model can be adapted to other RCTs remains an open question. Second, we obtained a large number of audio-recordings of consultations; however, most sites perceived these recordings as a barrier to conducting the trial, which was more prominent on sites that struggled to recruit. It is possible that our data collection had an embedded bias towards positive results because of hard-to-reach struggling sites. Efforts to overcome this shortcoming were made by including audio-recordings as an integral part of the recruitment process at the site initiation.

Findings from the FASHIoN trial QRI did not differ from other QRIs reported in the literature.[40,76] For example, our classification of the main recruitment issues reported in Phase I reflected those found in the qualitative research synthesis of Donovan *et al.*[40] Recruiters readily identified organisational difficulties and patients' preferences as key barriers to recruitment, but hidden issues emerged in relation to how comfortable recruiters were recruiting to this particular trial and their different levels

of equipoise. Another expected finding echoed previous research that focused on the importance of research teams working together.[76] Our view is that the TMG imparted strong messages about how to recruit, but good communication and relationships within the research teams made these messages bear fruit in terms of achieving recruitment targets.

Perhaps the most innovative aspects of this QRI were the recruitment training plan and the final survey evaluation. The six-step model provided a guide to create a comprehensive training programme and additional resources to address lack of recruitment experience and skills. We found evidence that the majority of recruiters used a structured model of recruitment in their conversation with patients and through the survey it was possible to discern which resources RAs valued the most.

More generally, this report shows that recruitment interventions tend to be multilayered and complex, and, as in the FASHIoN trial, interventions required the full support of, and commitment from, the TMG and participating site teams to be successful. What stands out in this work is how feasible it is to not only construct a well-crafted message promoting patient equipoise, but also to get a large number of researchers to use this message in their recruitment consultations. The effort of understanding and intervening on recruitment is worthwhile when answering important clinical questions.

Chapter 4 Results

Screening

A total of 6028 patients attending the participating surgeons' hip clinics were screened between 20 July 2012 and 15 July 2016 (*Figure 6*).

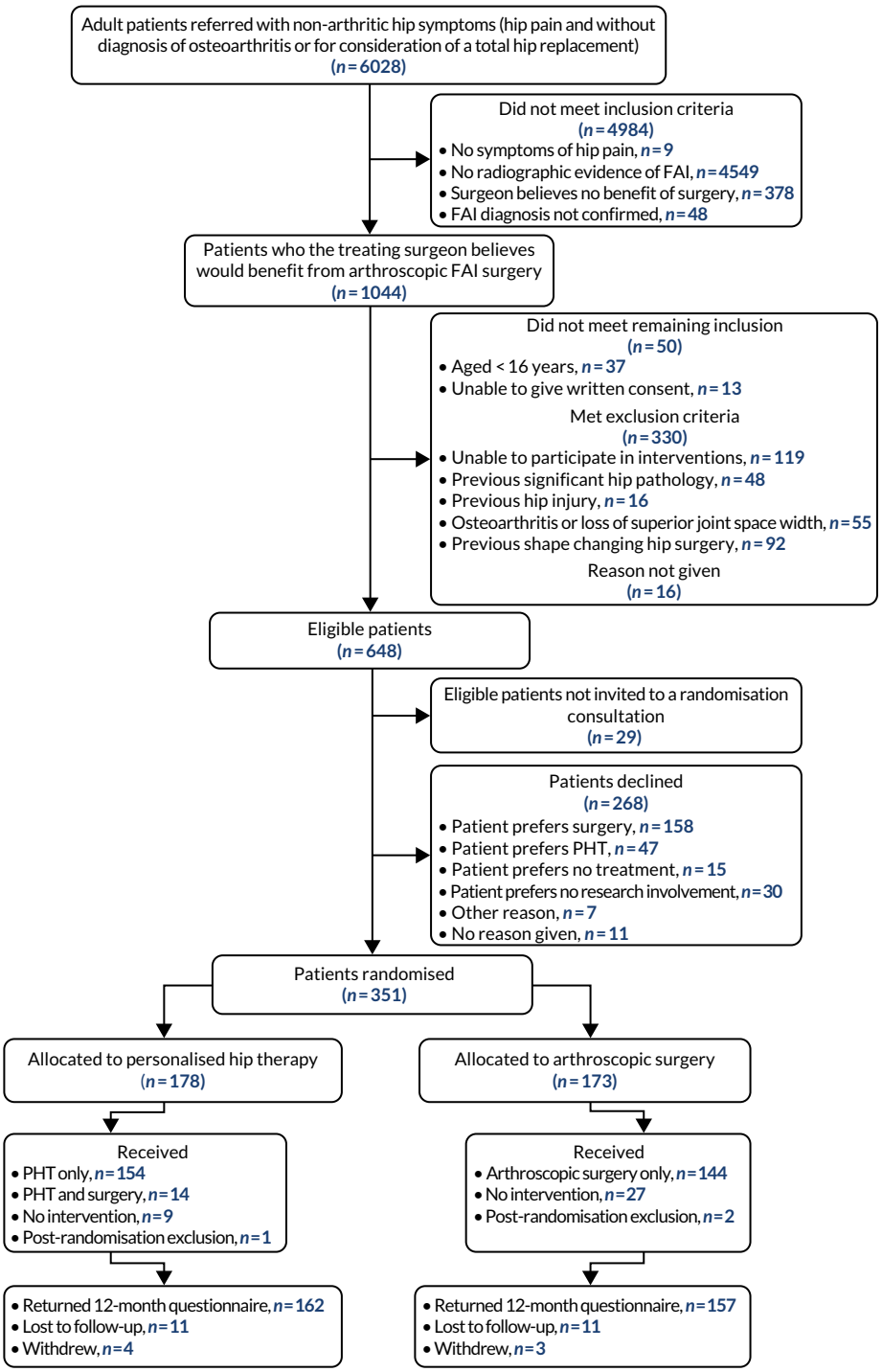

FIGURE 6 The FASHIoN study CONSORT flow diagram.

Recruitment

The number of patients approached and recruited by site is shown in *Table 6*. Overall, 94% of eligible participants were approached, 61% of whom consented to participate in the trial. In total, 351 participants were recruited. There were three participants who were randomised; however, post randomisation, these participants were found to not meet the inclusion criteria and were excluded and withdrawn from the study (referred to as post-randomisation exclusions). For the remainder of the report, data are presented for the 348 participants who were not post-randomisation exclusions. In total, 171 patients were allocated to hip arthroscopy and 177 patients were allocated to PHT.

TABLE 6 Numbers of eligible, approached and recruited participants by site

Site	Number of months open	Number of participants eligible	Number of participants approached	Number of participants recruited	Approach percentage (approached/ eligible, %)	Success percentage (recruited/ approached, %)
University Hospitals Coventry and Warwickshire	44	115	112	78	97	69
Yeovil District Hospital	42	38	37	22	97	59
Royal Devon and Exeter Hospital	41	22	22	18	100	82
Royal Orthopaedic Hospital	41	93	93	39	100	42
Wrightington Hospital	37	27	18	12	67	67
The Royal Cornwall	15	11	9	7	82	78
Elective Orthopaedic Centre	6	7	7	2	100	29
Northumbria Healthcare NHS Foundation Trust	36	57	55	14	96	25
The Royal London	15	8	8	5	100	63
Doncaster and Bassetlaw Teaching Hospital NHS Foundation Trust	36	32	28	16	88	57
Royal National Orthopaedic Hospital	35	15	13	10	87	77
Frimley Park Hospital	33	35	35	23	100	66
The Robert Jones and Agnes Hunt Orthopaedic Hospital	29	44	44	32	100	73
South Tees Hospitals NHS Foundation Trust	15	36	31	8	86	26
University College Hospital	14	15	15	8	100	53
Guys' and St Thomas' Hospital	13	31	31	11	100	35
Cardiff and Vale Hospitals	13	12	12	11	100	92

TABLE 6 Numbers of eligible, approached and recruited participants by site (*continued*)

Site	Number of months open	Number of participants eligible	Number of participants approached	Number of participants recruited	Approach percentage (approached/ eligible, %)	Success percentage (recruited/ approached, %)
Glasgow Royal Infirmary	11	5	5	5	100	100
Wrexham Maelor Hospital	13	4	4	4	100	100
King's College Hospital	13	22	22	13	100	59
North Bristol NHS Trust	10	13	13	7	100	54
Spire Manchester Hospital	4	4	4	3	100	75
Total		646	618	348	96	56

Screening data for only the main phase of study are presented.

Participant characteristics

The two treatment groups of consented participants were well matched in terms of both demographics and pre-randomisation hip-related quality of life (*Table 7*), with both groups of participants having had symptoms for approximately 3 years.

TABLE 7 Baseline demographic and clinical characteristics of all patients summarised by treatment group

Characteristic	Treatment group		Total
	Surgery ($N = 171$)[a]	PHT ($N = 177$)[a]	
Age (years)			
Mean	35.4	35.2	35.3
SD	9.7	9.4	9.6
Median	35.8	34.7	35.5
Minimum	16.7	16.4	16
Maximum	66.4	68.4	68.4
Hip side considered for treatment, *n* (%)			
Left	75 (44)	74 (42)	149 (43)
Right	95 (56)	103 (58)	198 (57)
Sex, *n* (%)			
Female	71 (42)	64 (36)	136 (39)
Male	100 (58)	113 (64)	215 (61)
Current smoking status, *n* (%)			
Yes	31 (18)	25 (14)	56 (16)
No	136 (80)	151 (85)	287 (82)

continued

TABLE 7 Baseline demographic and clinical characteristics of all patients summarised by treatment group (*continued*)

Characteristic	Treatment group		Total
	Surgery (*N* = 171)[a]	PHT (*N* = 177)[a]	
If yes, how many cigarettes smoked, on average, per day			
Mean	10	10	10
SD	5.4	4.6	5.1
Median	10	10	10
Minimum	2	2	2
Maximum	20	20	20
If yes, total number of years as a smoker			
Mean	17	14	16
SD	9.7	8.1	9.1
Median	15	15	15
Minimum	1	1	1
Maximum	36	26	36
Duration (months) of hip symptoms			
Mean	37	40	39
SD	36.6	40.8	38.6
Median	24	24	24
Minimum	0	4	0
Maximum	228	240	240
Impingement type, *n* (%)			
Cam	129 (75)	133 (75)	262 (75)
Mixed	29 (17)	30 (17)	59 (17)
Pincer	13 (8)	14 (8)	27 (8)
Units of alcohol consumed in an average week			
Mean	6.2	6.0	6.1
SD	8.6	7.7	8.1
Median	2	3	3
Minimum	0	0	0
Maximum	40	40	40
Diabetes, *n* (%)			
Yes	2 (1)	4 (2)	6 (2)
No	165 (96)	171 (97)	336 (97)
Chronic renal failure, *n* (%)			
Yes	1 (1)	0 (0)	1 (< 1)
No	166 (96)	176 (99)	342 (97)
Physical activity (UCLA Activity Scale)			
Mean	4.3	4.4	4.3
SD	2.5	2.5	2.5
Median	5	5	5
Minimum	1	1	1
Maximum	9	9	9

TABLE 7 Baseline demographic and clinical characteristics of all patients summarised by treatment group (*continued*)

Characteristic	Treatment group		Total
	Surgery ($N = 171$)[a]	PHT ($N = 177$)[a]	
Hip-related quality of life (iHOT-33 score)			
Mean	39	36	37
SD	20.9	18.2	20.0
Median	38	33	37
Minimum	0	2	0
Maximum	82	80	82
SF-12: physical component score			
Mean	44	44	44
SD	7.6	5.9	6.8
Median	44	44	44
Minimum	24	29	24
Maximum	61	63	63
SF-12: mental component score			
Mean	42	42	42
SD	7.1	7.3	7.2
Median	43	43	43
Minimum	24	18	18
Maximum	61	57	61
EQ-5D-3L/EQ-5D-5L index score			
Mean	0.576	0.557	0.566
SD	0.26	0.25	0.25
Median	0.689	0.642	0.654
Minimum	−0.239	−0.181	−0.239
Maximum	1	1	1
EQ-5D-5L VAS			
Mean	67	67	67
SD	20.2	18.7	19.4
Median	70	70	70
Minimum	5	10	5
Maximum	100	100	100

UCLA, University of California, Los Angeles.
a Where numbers do not total to treatment group this indicates that data were missing.

Treatment allocation and adherence

The adherence to treatment allocation is displayed in *Table 8* with reasons for not adhering to allocation given in *Appendix 2*. With respect to treatment adherence, adherence to PHT was considered to be attending at least one session with the PHT physiotherapist.

Fourteen participants who were allocated to PHT had all or part of this intervention, but then, at their request, went on to have hip arthroscopy within 12 months after randomisation. No patients allocated

TABLE 8 Treatment adherence (randomised treatment vs. treatment received) at 12 months post randomisation

	Treatment allocated, *n* (%)		
Treatment received	Surgery	PHT	Total
Surgery only	144 (84)	0 (0)	144
PHT only	0 (0)	154 (87)	154
PHT and surgery	0 (0)	14 (8)	14
Neither trial treatment	27 (16)	9 (5)	36
Total	171	177	348

to hip arthroscopy had PHT. Twenty-seven participants allocated to surgery did not receive surgery within the 12-month follow-up period.

Patients allocated to PHT were able to commence their treatment a mean of 48 days after randomisation, whereas patients allocated surgery did not commence their treatment until a mean of 132 days after randomisation (*Table 9* and *Figure 7*).

Interventions

Arthroscopic surgery

Surgeons

Surgery was delivered by 1 out of 27 consultants registered with the General Medical Council and on the specialty trauma and orthopaedic register. Surgeons had been on the specialty register for a mean of 11 (SD 7) years. Trial surgeons had been performing hip arthroscopy as a consultant for a mean of 9 (SD 3.6) years, having received the following dedicated hip preservation training: specialist registrar ($n = 13$), courses ($n = 24$), fellowship ($n = 14$, mean duration 9 months) and travelling fellowship ($n = 8$, mean duration 1.6 months). Six surgeons were directors of hip preservation fellowships and 17 surgeons were faculty on dedicated hip arthroscopy courses. Trial surgeons performed a mean of 112 (SD 55) hip arthroscopies per year, of which 81 (SD 45) were for FAI syndrome. Each surgeon treated a mean of 5.3 (SD 5.3) patients with surgery within the FASHIoN trial (*Table 10*).

TABLE 9 Summary of timing from day of randomisation to date at which intervention started, for those who received allocated treatment

	Days between date of randomisation and date of intervention	
	Surgery group	PHT group
Mean	132	48
n	144	154
SD	71	43
Median	122	37
Minimum	11	0
Maximum	359	245

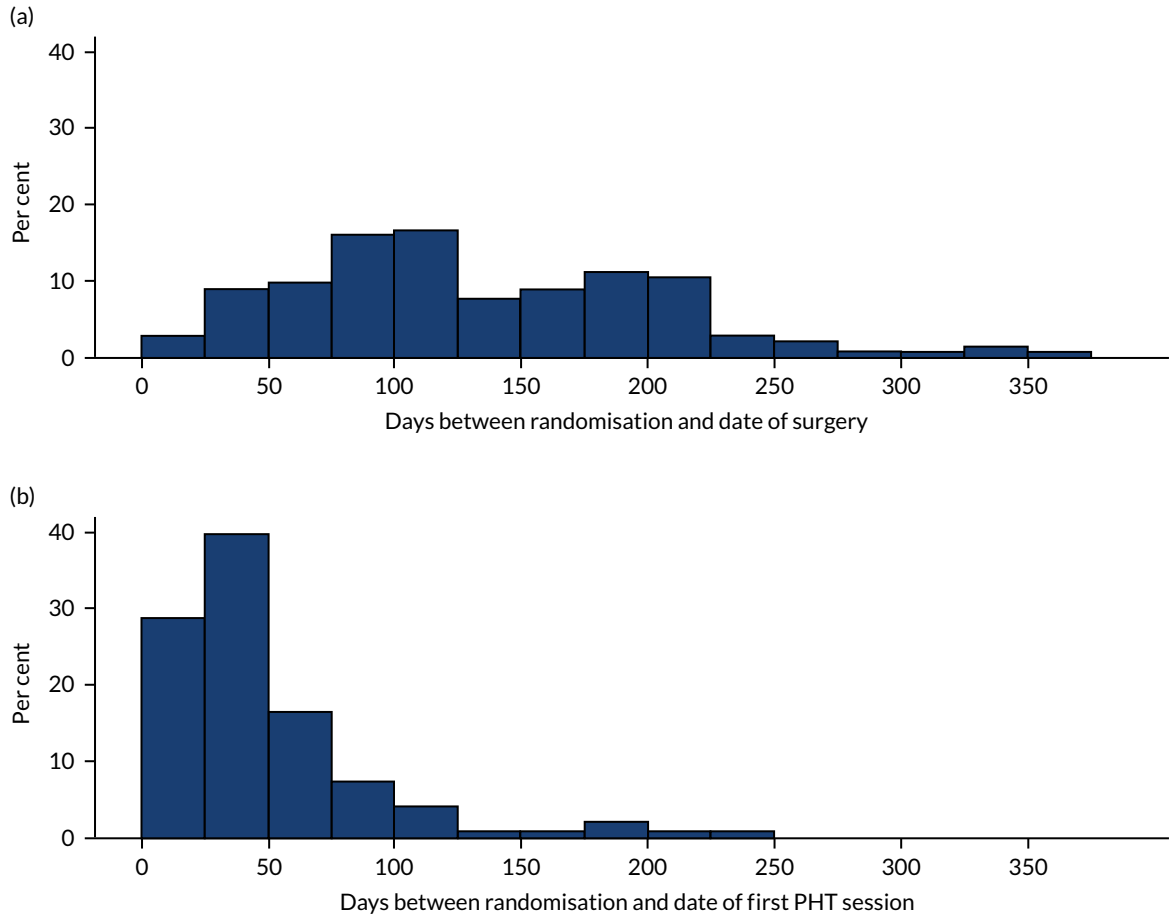

FIGURE 7 Delay from day of randomisation to date at which intervention started, for those who received allocated treatment. (a) Surgery; and (b) PHT.

TABLE 10 Number of participants treated by each surgeon

	Number of participants treated
Mean	5
SD	5
Median	3
Minimum	1
Maximum	21

Surgery performed

A total of 144 patients received arthroscopic hip surgery. Twenty-seven patients allocated to hip arthroscopy did not have surgery in the 12-month follow-up period. A total of 121 patients received postoperative MRI. In 141 operations the surgeon examined the central compartment of the hip (note that three patients had no details available) and in 140 operations the peripheral compartment of the hip was examined (note that four patients had no details available). A cam reshaping was undertaken in isolation in 103 patients, a pincer reshaping in eight patients, cam and pincer reshaping in 27 patients, and in four patients no reshaping was undertaken, as the hip was found to be degenerate. In two patients the reshaping was not detailed.

Postoperative rehabilitation

A total of 141 patients received the surgeons' routine postoperative rehabilitation. There was a high degree of heterogeneity in the postoperative rehabilitation protocols between sites. Details on the postoperative rehabilitation are available in *Appendix 2*. Postoperative rehabilitation was most typically structured in stages over several months and included:

- an immediate postoperative phase that restored hip movement as pain improved
- a phase to restore static stability and movement
- a phase to restore dynamic stability and movement
- sports-specific training.

Surgical fidelity

Of those who received surgery, 84% (121/144) had a postoperative MRI and their case was assessed by the surgical review panel. Of these cases, 87% (105/121) were deemed satisfactory and 13% (16/121) were deemed unsatisfactory. The most common reason for unsatisfactory surgery was an inadequate bony resection ($n = 7$) and a sharp transition from the femoral head to neck ($n = 5$) as a result of reshaping surgery. *Table 11* reports the grading for postoperative hip shape (see also *Appendix 1*).

Personalised hip therapy

Physiotherapists

Personalised hip therapy was delivered at 23 hospitals by a total of 47 chartered physiotherapists who were registered with the Health and Care Professions Council (London, UK). In terms of clinical experience, experience ranged from NHS Agenda for Change band 5 to band 8a (band 5, $n = 1$; band 6, $n = 11$; band 7, $n = 19$; band 8a, $n = 5$; band unknown, $n = 11$). Agenda for Change is the current NHS grading and pay system in which a band 5 physiotherapist is usually a recently qualified physiotherapist or one with < 3 years of experience and a band 8a physiotherapist represents a specialist physiotherapist or an extended scope practitioner.

All PHT physiotherapists treated patients with musculoskeletal conditions within their normal clinical practice. Forty-one (90%) physiotherapists had previously treated patients with FAI syndrome before involvement in the trial. All physiotherapists attended at least one of eight workshops held between 2012 and March 2016. Physiotherapists delivered a median of seven PHT sessions and each physiotherapist treated a median of two patients (*Table 12*). Typically, each site had two trained PHT physiotherapists and they often changed jobs and, therefore, the median number of participants treated by each PHT physiotherapist was smaller than that of participants operated on by each surgeon.

Personalised hip therapy delivered

The physiotherapists delivered a total of 947 PHT treatment contacts for trial participants, of which 878 (93%) were face-to-face contacts, 31 (3%) were telephone contacts and 4 (0.4%) were contacts via e-mail. For 34 (3%) contacts, physiotherapists did not record the mode of contact on the CRF. Analysis of the CRF data highlighted that 72 (65%) patients randomised to the PHT intervention received six or more treatment contacts in accordance with the PHT protocol. Fifty-six (35%) patients

TABLE 11 Grading of surgical quality

	Grade			
	1 (satisfactory)	2 (borderline)	3 (inadequate)	4 (no change)
Head sphericity	80	29	9	2
Head–neck junction	73	38	7	2
Rim morphology	109	7	0	2

TABLE 12 Number of sessions delivered, and participants treated, by each PHT therapist ($N = 47$)

	Number of sessions delivered	Number of participants treated
Mean	16	3
SD	27	4.1
Median	7	2
Minimum	1	1
Maximum	187	28

received fewer than six treatment sessions. Of these patients, nine (16%) were formally discharged by the physiotherapist and 47 (84%) were not. Only 20 (11%) participants failed to attend any session of their PHT treatment, with a further 23 (13%) participants receiving fewer than three treatment contacts (*Table 13* and *Appendix 2*).

Treatment sessions lasted a mean of 30 minutes (SD 11 minutes), with the first assessment and treatment session usually lasting longer. The content of treatment sessions included assessment or reassessment (in 88% of treatment sessions), education and advice (in 77% of sessions) and help with pain relief (in 74% of treatment sessions). There was evidence that the participant's exercise programme was supervised in clinic in 78% of treatment sessions and that exercise diaries were used with 46% of participants to support monitoring of exercise behaviour at home, although in 4% of cases the exercise diary was forgotten by participants at further treatment sessions.

In terms of the specific content of the PHT exercise prescription for participants, for 158 PHT participants there was a total of 3657 exercises recorded on the CRFs from 947 treatment sessions (highlighting that most participants were prescribed three or four different exercises at each treatment session). A detailed summary of the frequency of each exercise prescribed is provided in *Appendix 2*. The five most frequent exercises prescribed were (1) bridge ($n = 337$), (2) clam ($n = 326$), (3) bent knee fall out ($n = 226$), (4) straight leg raise through hip abduction in side lying ($n = 186$) and (5) hip extension in four-point kneeling ($n = 172$). These five most commonly prescribed exercises (i.e. exercises 4, 7, 3, 8 and 5, respectively) aim to establish pelvic control while strengthening the gluteus maximus and gluteus medius. Other frequently prescribed exercises were stretches targeting the hip flexors and external rotators (see *Appendix 2*).

TABLE 13 Number of PHT sessions attended

Number of sessions attended	Count, *n* (%)	Cumulative, *n* (%)
1	17 (11)	17 (11)
2	6 (4)	23 (15)
3	10 (6)	33 (21)
4	13 (8)	46 (29)
5	10 (6)	56 (35)
6	32 (20)	88 (56)
7	18 (11)	106 (67)
8	20 (13)	126 (80)
9	14 (9)	140 (89)
10	16 (10)	156 (99)
11	2 (1)	158 (100)
Total	158	158

Personalised hip therapy fidelity

A source verification audit was undertaken, with 19 sites visited. Seventy-three (41%) study patients' physiotherapy treatment notes were reviewed and compared with the data recorded on CRFs. All CRFs were judged to accurately reflect the treatment documented in the treatment record. These data were then shared with the central fidelity review panel on a per case basis.

Of the patients who received PHT ($n = 154$), 107 (69%) were judged to have received the intervention to a high fidelity. The most common reason for the low fidelity of PHT was participants not receiving the minimum of six therapy sessions (34/47, 72%). Other reasons for the low fidelity of PHT were no progression of exercises by the physiotherapist (11/47, 23%) and the patient not complying with the exercise programme (2/47, 4%).

Outcome data completeness

A total of 319 (92%) participants completed questionnaires at 12 months after randomisation, seven participants withdrew from follow-up questionnaire completion and 22 participants were lost to follow-up (*Table 14*). *Table 15* highlights the timings of follow-up assessments by treatment group. *Appendix 2*, *Table 46*, reports the completeness of the questionnaire data at different time points.

TABLE 14 Follow-up status at time points in the FASHIoN trial

	6-month follow-up, *n* (%)			12-month follow-up, *n* (%)		
Follow-up status	**Surgery group**	**PHT group**	**Total**	**Surgery group**	**PHT group**	**Total**
Completed questionnaire	160 (92)	154 (87)	314 (89)	158 (92)	163 (92)	321 (92)
Loss to follow-up	8 (5)	19 (11)	27 (8)	10 (6)	10 (6)	20 (6)
Consent withdrawn	3 (2)	4 (2)	7 (2)	3 (2)	4 (2)	7 (2)

TABLE 15 Summary of timing of follow-up assessments, by treatment arm

	Treatment group	
Timing of follow-up assessment	**Surgery**	**PHT**
Days between date of randomisation and date of 6-month follow-up form		
Mean	190	190
n	161	154
SD	36	35
Median	186	185
Minimum	71	83
Maximum	307	296
Days between date of randomisation and date of 12-month follow-up form		
Mean	370	379
n	158	163
SD	30.7	54.5
Median	362	364
Minimum	292	264
Maximum	470	812

Outcomes

Primary outcome

The iHOT-33 score increased between baseline and 12 months in both groups (*Table 16* and *Figures 8* and *9*). iHOT-33 scores improved from a mean of 36 points at baseline to 50 points at 12 months in the PHT group and from a mean of 39 points at baseline to 59 points at 12 months in the hip arthroscopy group. In the primary intention-to-treat analysis at 12 months, the adjusted estimate of treatment effect measured with iHOT-33 was 6.8 (95% CI 1.7 to 12.0) in favour of the hip arthroscopy group compared with the PHT group. The *p*-value of 0.009 indicates that there is evidence for a statistically significant difference (the 95% CI includes the prespecified MCID and does not include zero).

Secondary outcomes

There were no were significant differences between treatment groups at 6 or 12 months in the EuroQol-5 Dimensions (EQ-5D) or SF-12 (*Figures 10–13* and *Table 17*).

Per-protocol analyses

Two per-protocol analyses were conducted. The first per-protocol analysis was for patients who received surgery only ($n = 144$) or PHT only ($n = 154$), irrespective of the quality of the treatment they received (*Table 18*). The adjusted estimate of treatment effect measured with iHOT-33 was 8.2 (95% CI 2.8 to 13.6) in favour of hip arthroscopy.

TABLE 16 Summary statistics, unadjusted and adjusted treatment effects at all time points based on an intention-to-treat analysis: iHOT-33

	Treatment group						
	Surgery		PHT		Difference (95% CI)		
Time point	Mean (SD)	*n*	Mean (SD)	*n*	Raw	Adjusted[a]	*p*-value
6 months	46.6 (25)	161	45.6 (23)	154	1.0	−0.7 (−5.2 to 3.7)	0.743
12 months	58.8 (27)	158	49.7 (25)	163	9.1	6.8 (1.7 to 12.0)	0.009

a Mixed-effects regression model based on intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.

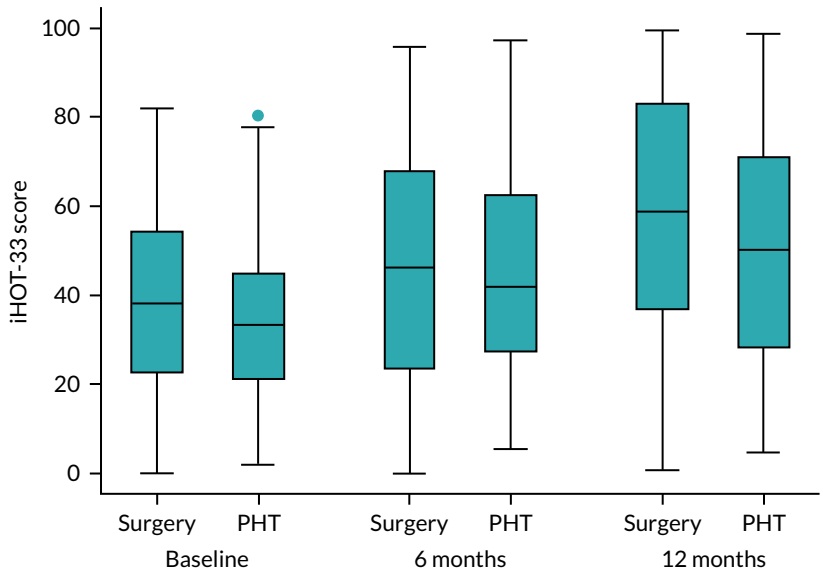

FIGURE 8 Box plots of iHOT-33 baseline and follow-up scores.

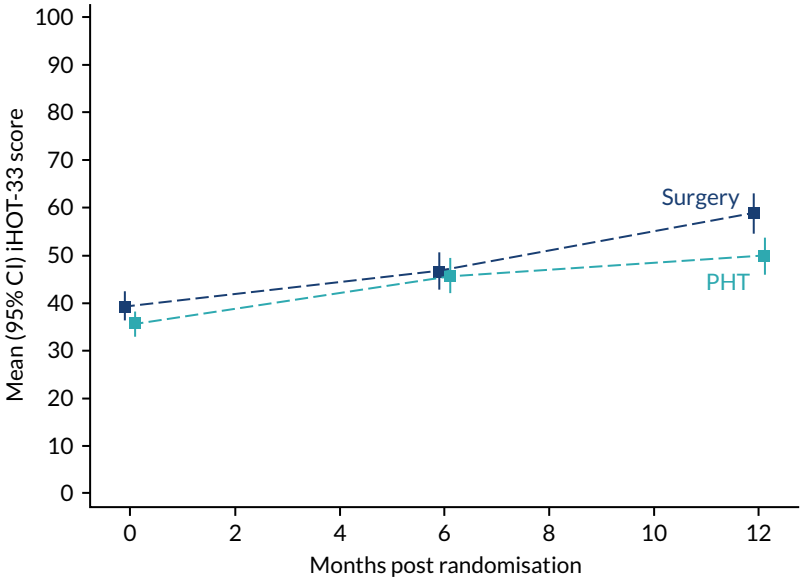

FIGURE 9 Overall trend in iHOT-33 unadjusted mean scores and 95% CIs.

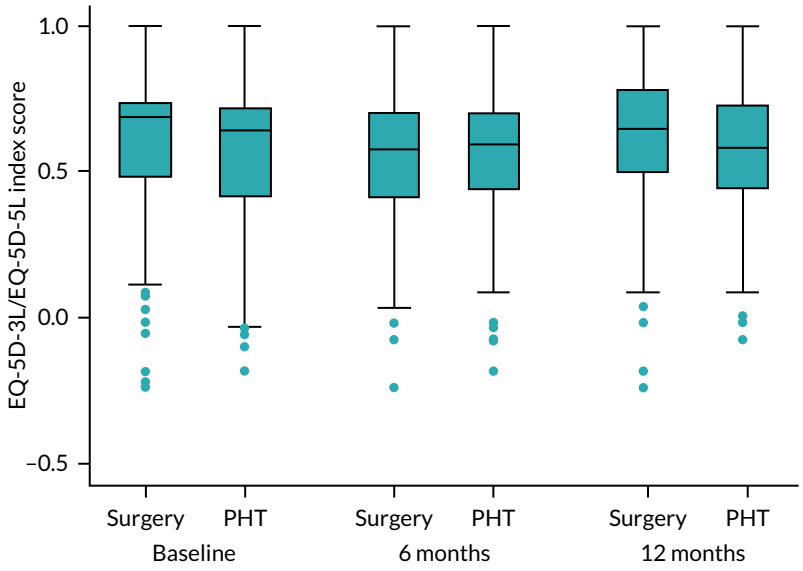

FIGURE 10 Box plots of EQ-5D-5L baseline and follow-up scores.

A second exploratory per-protocol analysis was conducted that included only those participants who received their allocated intervention and whose treatment was deemed to be of a satisfactory quality by the respective review panels. In this analysis, 95 surgical cases and 106 PHT participants were included (*Table 19*). In this exploratory per-protocol analysis, the adjusted estimate of treatment effect measured with the iHOT-33 was favour of surgery (*Table 20*).

Missing outcome analyses

There was a low level of missing item-level data in all patient-reported outcome measures at all time points. After imputation for missing data, the adjusted estimate of treatment effect was similar at 6.6 (95% CI 1.7 to 11.4) points in favour of hip arthroscopy (*Table 21*).

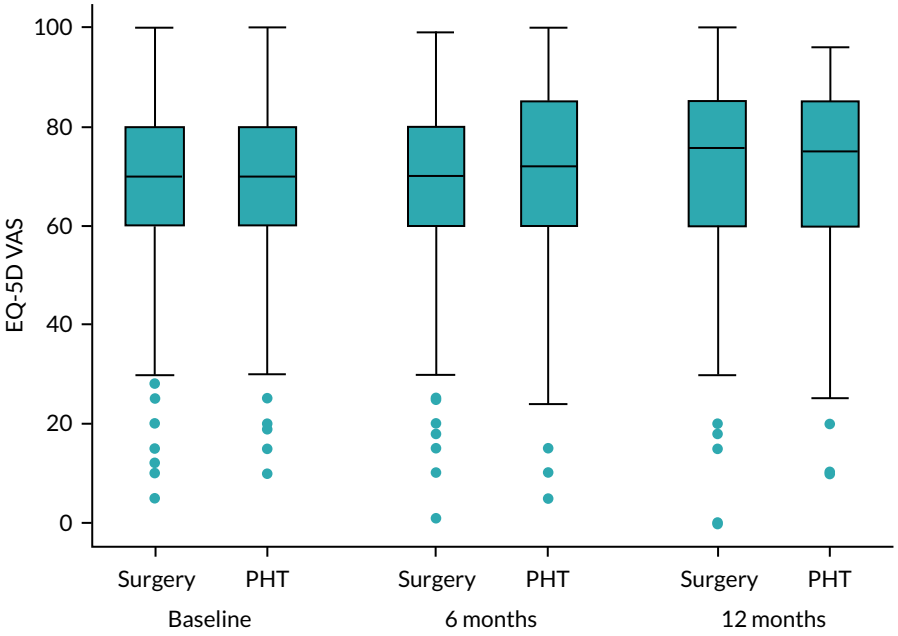

FIGURE 11 Box plots of EQ-5D VAS baseline and follow-up scores.

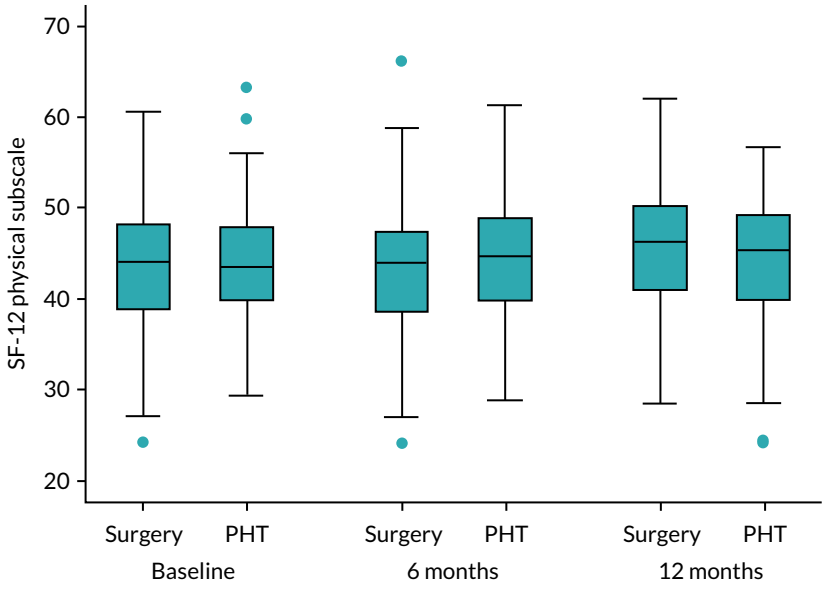

FIGURE 12 Box plots of SF-12 (physical component score) baseline and follow-up scores.

Subgroup analyses

Planned subgroup analyses were conducted for those participants with cam, pincer and mixed-type FAI syndrome and those aged < 40 years and ≥ 40 years.

There was no evidence of a subgroup effect, with the adjusted estimate of treatment effect measured by the iHOT-33 being as follows: 5.0 (95% CI −1.2 to 11.3) in participants aged < 40 years, 10.9 (95% CI 1.7 to 20.1) in participants aged ≥ 40 years, 8.3 (95% CI 2.5 to 14.2) in participants with cam morphology, 1.1 (95% CI −11.5 to 13.7) in participants with mixed cam and pincer morphology and 4.0 (95% CI −14.6 to 22.7) in participants with pincer morphology, in favour of surgery (*Table 22*).

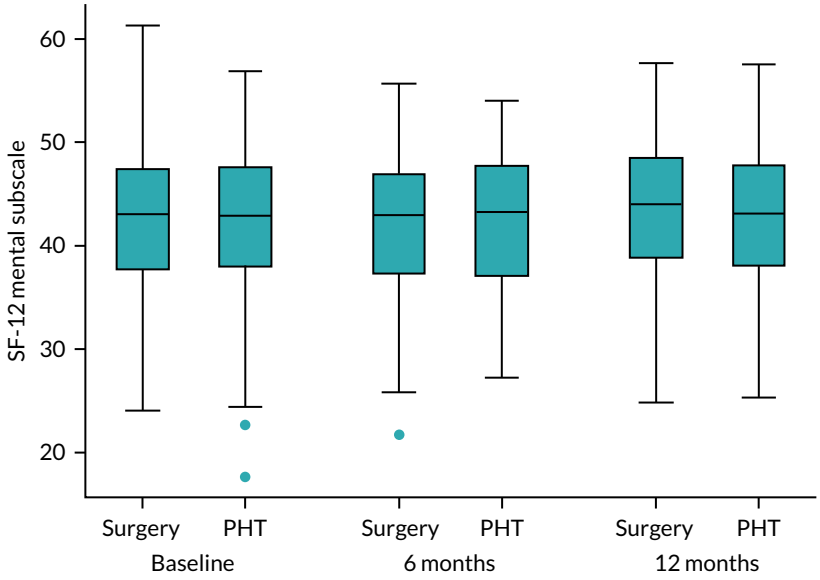

FIGURE 13 Box plots of SF-12 (mental component score) baseline and follow-up scores.

TABLE 17 Summary statistics, unadjusted and adjusted treatment effects at all time points based on an intention-to-treat analysis: EQ-5D-5L and SF-12

Outcome	Time point (months)	Treatment group: Surgery Mean (SD)	Surgery *n*	PHT Mean (SD)	PHT *n*	Difference (95% CI): Raw	Difference (95% CI): Adjusted[a]	*p*-value
EQ-5D-5L score	6	0.544 (0.26)	144	0.573 (0.23)	147	−0.029	−0.042 (−0.088 to 0.005)	0.081
	12	0.615 (0.25)	152	0.578 (0.24)	147	0.037	0.020 (−0.027 to 0.067)	0.397
EQ-5D VAS score	6	67.8	145	70.3	145	−2.5	−2.1 (−5.7 to 1.4)	0.241
	12	71.9	150	69.2	145	2.7	2.6 (−1.2 to 6.4)	0.180
SF-12 physical component score	6	43.4	146	44.2	142	−0.8	−0.7 (−2.1 to 0.7)	0.304
	12	45.1	145	44.1	132	1.0	1.1 (−0.2 to 2.5)	0.099
SF-12 mental component score	6	42.1	146	42.1	142	−0.1	−0.1 (−1.5 to 1.3)	0.929
	12	43.2	145	42.6	132	0.6	0.4 (−1.2 to 2.0)	0.589

a Mixed-effects regression model based on an intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.

TABLE 18 Summary statistics, unadjusted and adjusted treatment effects at all time points based on a per-treatment analysis: iHOT-33

Time point	Treatment group: Surgery Mean (SD)	Surgery *n*	PHT Mean (SD)	PHT *n*	Difference (95% CI): Raw	Difference (95% CI): Adjusted[a]	*p*-value
12 months	58.5 (27.9)	140	49.3 (25.4)	147	9.2	8.2 (2.8 to 13.6)	0.003

a Mixed-effects regression model based on an intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.

TABLE 19 Participants included in second per-protocol analysis, including the results of the quality review panel

	Treatment allocated, *n* (%)		
Treatment received	**Surgery**	**PHT**	**Total**
Adequate	95 (56)	106 (60)	201 (58)
Not adequate	45 (26)	39 (22)	84 (24)
Received other treatment	27 (16)	23 (13)	50 (14)
Missing review	4 (2)	9 (5)	13 (4)
Total	171	177	348

TABLE 20 Summary statistics, unadjusted and adjusted treatment effects at all time points based on the second per-protocol analysis: iHOT-33

	Treatment group						
	Surgery		PHT		Difference (95% CI)		
Time point	**Mean (SD)**	***n***	**Mean (SD)**	***n***	**Raw**	**Adjusted[a]**	***p*-value**
12 months	56.9 (28.2)	92	49.3 (25.9)	104	7.6	6.9 (0.26 to 13.4)	0.041

a Mixed-effects regression model based on an intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.

TABLE 21 Means and SDs of the primary outcome at all time points and estimated treatment effects after adjustment, using a multiple imputation approach to missing iHOT-33 overall scores

	Treatment group						
	Surgery		PHT		Difference (95% CI)		
Time point	**Mean (SD)**	***n***	**Mean (SD)**	***n***	**Raw**	**Adjusted[a]**	***p*-value**
12 months	58.7 (26.2)	171	49.8 (24.6)	177	8.9	6.6 (1.7 to 11.4)	0.008

a Mixed-effects regression model based on an intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.

Sensitivity analyses

In a post hoc analysis, there was no significant difference in iHOT-33 score at 12 months for patients in the hip arthroscopy group who were treated within 6 months of randomisation compared with those treated $\geq$ 6 months after randomisation (0.9, 95% CI −10.7 to 8.8).

Complications

Complications at the 6-week assessment

A total of 138 and 146 participants following surgery and PHT, respectively, returned a 6-week complication log. The most commonly reported complication in both groups was muscle soreness (*Table 23*). Eight (6%) patients reported a superficial wound infection following surgery, but antibiotics were prescribed in only four (3%) cases. Thirty-five (24%) participants reported groin, leg or foot numbness after surgery.

TABLE 22 Results of the subgroup analysis of the iHOT-33 showing means and SDs at 12 months post randomisation and estimated treatment effects after adjustment

	Treatment group						
	Surgery		PHT		Difference (95% CI)		
Subgroup	Mean (SD)	*n*	Mean (SD)	*n*	Raw	Adjusted[a]	*p*-value[b]
Age group							
< 40 years	59.1 (26.6)	103	50.0 (24.5)	117	9.1	5.0 (−1.2 to 11.3)	0.302
≥ 40 years	58.1 (28.4)	55	48.8 (27.9)	46	9.3	10.9 (1.7 to 20.1)	
Impingement type							
Cam	59.4 (27.7)	120	49.1 (24.3)	124	10.4	8.3 (2.5 to 14.2)	0.567
Mixed	56.3 (22.4)	26	51.5 (31.1)	27	4.8	1.1 (−11.5 to 13.7)	
Pincer	57.3 (33.4)	12	51.8 (25.4)	12	5.5	4.0 (−14.6 to 22.7)	

a Mixed-effects regression model based on an intention-to-treat analysis approach with allocated treatment group, impingement type, sex and baseline iHOT-33 score as fixed effects, and recruiting site as a random effect.
b *p*-values are of the interaction term between the variable of interest and treatment in the model.

TABLE 23 Patient-reported complications at 6 weeks post intervention

	Treatment group, *n* (%)	
Complication	Surgery (*N* = 138)	PHT (*N* = 146)
Patient-reported superficial wound infection	8 (6)	n/a
Requiring antibiotic prescription	4 (3)	n/a
Deep-wound infection	0	n/a
Requiring further surgery	0	n/a
Patient-reported numbness in groin, leg or foot	35 (24)	n/a
Hip fracture	0	n/a
Further surgery following hip arthroscopy	0	n/a
Problems with pain medication	10 (7)	7 (5)
Problems with hip joint injections	0	5 (3)
Muscle soreness from exercises	57 (41)	68 (47)
Deep-vein thrombosis	0	0
Unscheduled hospital appointments	5 (4)	2 (1)
Persistent hip-related symptoms	11 (8)	9 (6)
Other complications related to intervention	6 (4)	3 (12)
Other complications not related to intervention	5 (4)	10 (7)
Of which patient reported lower back pain	2 (2)	5 (3)

n/a, not applicable.

Complications reported at the 6- and 12-month follow-up time points

Complications at 12 months post randomisation are reported in *Table 24*.

At 12 months, seven SAEs had been reported, six of which were in patients who received surgery (*Table 25*). Two patients allocated to surgery required hospitalisation and four required further medical intervention. One patient who received PHT required hospitalisation.

Three-year follow-up: further procedures or physiotherapy

In the 24-month period from 12 to 36 months post randomisation, about one-third of all patients had a further procedure and about half had further physiotherapy sessions (*Tables 26* and *27*). A (further) one-quarter of PHT patients chose to have a hip arthroscopy and 12% of hip arthroscopy patients had a further hip arthroscopy. Two per cent and 7% of the patients in surgery and PHT groups, respectively, had a hip replacement.

TABLE 24 Patient-reported AEs at 12 months

AE	Treatment group		*p*-value[c]
	Surgery ($n = 138$[a])	PHT ($n = 146$[b])	
Numbness in groin, leg or foot	35	n/a	n/a
Superficial wound problems	9 (4 required antibiotics)	n/a	n/a
Deep infection	1	n/a	n/a
Fracture	0	n/a	n/a
Deep-vein thrombosis	0	n/a	n/a
Muscle soreness at 6 weeks post intervention	58	69	0.404
Hip pain or stiffness at 6 weeks post intervention	13	8	0.258
Unscheduled hospital appointments	13	6	0.096
Other complications related to intervention	8 (2 numbness proximal thigh, 1 scrotal infection, 1 scrotal bruising, 1 labial swelling, 1 ankle pain, 1 erratic INR, 1 nausea secondary to analgesia and 1 numbness to tip of tongue for 2 weeks post operation)[d]	1 (muscle spasms)	0.0168
Other complications not related to intervention	10 (3 knee pain, 2 lower back pain, 1 shingles, 1 UTI, 1 essential thrombocythaemia, 1 hernia surgery and 1 contralateral foot pain)	18 (7 lower back pain, 2 knee pain, 2 road traffic collisions, 2 abdominal pain under investigation, 1 viral illness, 1 endometriosis, 1 chronic pain referred to rheumatologist, 1 skin discolouration and 1 multiple sclerosis)	0.168

INR, international normalised ratio; n/a, not applicable; UTI, urinary tract infection.
a Six patients did not complete the complication form.
b Eight patients did not return the complication form.
c *p*-values based on Fisher's exact test.
d There were nine other complications related to the intervention in eight patients.

TABLE 25 Number and description of SAEs by treatment arm

Treatment group	SAE	*p*-value[a]
Surgery ($n = 138$)	6 (1 failed discharge from day surgery unit required overnight admission, 1 scrotal haematoma required readmission, 2 superficial wound infection required oral antibiotics, 1 deep infection required further surgery and ultimately a total hip replacement and 1 fall unrelated to surgery)	0.060
PHT ($n = 146$)	1 (biliary sepsis unrelated to PHT)	

a *p*-values based on Fisher's exact test.

TABLE 26 Number and details of further surgical procedures at 3 years post randomisation, by treatment arm

Surgical procedure	Surgery ($N = 154$), *n* (%)	PHT ($N = 157$), *n* (%)
Any procedure	46 (30)	51 (32)
Hip arthroscopy	19 (12)	38 (24)
Hip replacement	3 (2)	11 (7)
Hip injection	24 (16)	6 (4)
Other procedure	1 (1)	1 (1)

TABLE 27 Number and details of further physiotherapy sessions at 3 years post randomisation, by treatment arm

Physiotherapy session	Surgery ($N = 154$), *n*	PHT ($N = 157$), *n*
Any treatment	91	78
If yes, setting		
NHS treatment	74	60
Private treatment	17	18
If yes, type of treatment		
Exercises	66	52
Other	25	26
If yes, number (SD) of sessions	8.8 (10)	8.9 (7)

Chapter 5 Economic evaluation results

Study population

The study sample comprised a total of 351 patients, of whom 173 patients were randomised to receive surgery and 178 patients were randomised to receive PHT. Three patients (two from the surgery group and one from the PHT group) were excluded post randomisation. The final sample, therefore, consisted of 348 patients (surgery group, $n = 171$; PHT group, $n = 177$). At baseline, completion rates for resource use data were between 96.5% and 99.8% in the surgery group and between 98.9% and 99.4% in the PHT group. At the 6-month assessment point, completion rates for resource use data were between 82% and 84% in the surgery group and between 78% and 81% in the PHT group. At the 12-month assessment point, completion rates for resource use data were between 83% and 87% in the surgery group and between 73% and 78% in the PHT group (*Table 28*). Health utility values were derived from the EQ-5D-3L/EQ-5D-5L and the SF-6D (via SF-12) and were available from > 98%, 79% and > 74% of patients from both groups at baseline, the 6-month assessment point and the 12-month assessment point, respectively.

Assessment of resource use and costs results

Cost of personalised hip therapy

Table 29 summarises PHT attendance by type of consultation, impingement classification, missed appointments and recruitment site. A total of 1219 physiotherapy appointments were offered to 166 (94%) of the 177 patients in the PHT group. Of these patients, 909 (75%) were face-to-face consultations, 38 (3%) were telephone consultations, seven (0.6%) were e-mail contacts and 256 (21.2%) were recorded as unknown or missed appointments. A total of 166 (94%) of the 177 PHT patients had at least one physiotherapy contact, 105 (59%) had six or more contacts (as recommended in the treatment protocol for PHT) and 11 (6.2%) did not receive the intervention at all. Excluding missed appointments, the mean number of physiotherapy contacts per patient was 5.6 (range 1–11) and the mean duration of contact for all sessions attended was 178.2 (range 30–375) minutes per patient. Among those who had the recommended six or more physiotherapy contacts, the mean number of contacts per patient was 7.7 (range 6–11) and the mean total duration across all sessions attended was 222.6 (range 140–375) minutes per patient.

A total of 225 out of the 1219 PHT appointments offered were missed by 94 patients (53% of the PHT sample), giving an overall non-attendance rate of 18.5%. Among the 94 patients who missed an appointment, the mean number of appointments missed was 2.3 per patient, the mean total duration of all appointments missed was 75.4 minutes and the mean total cost of missed physiotherapy time was £65.60 per patient. The mean cost of PHT was £192.16 per patient, including missed appointments, and £155.01 per patient, excluding missed appointments. Among those attending six or more consultations, the mean cost of PHT was £196.56 per patient, including missed appointments, and £193.65 per patient, excluding missed appointments.

Resource use and cost of arthroscopic surgery for FAI

Resource use data associated with the delivery of arthroscopic surgery for FAI were collected for 47 (27%) of the 173 patients in the surgery group and one patient in the PHT group across 18 (82%) of the 22 orthopaedic centres participating in the study. (Note that the one patient in the PHT group was randomised to PHT, but had surgery immediately after the 12-month follow-up period had ended.) Six (13%) of 46 patients were excluded because data on duration of surgery and/or post-surgical inpatient length of stay were missing. The mean age among the remaining 40 patients included in the

TABLE 28 Completion rates for resource use variables and quality-of-life outcomes

Assessment point and resource use category	Completion rate (%)	
	Surgery ($n = 171$)	PHT ($n = 177$)
Baseline		
Hospital inpatient care	98.8	99.4
Hospital outpatient attendances	98.8	98.9
Community health-care services	98.8	98.9
Social care services	98.2	99.4
Medications	96.5	99.4
Aids and adaptations	97.7	99.4
Additional (indirect) costs	98.8	99.4
Benefit payments	98.8	99.4
EQ-5D-3L/EQ-5D-5L utility values	98.2	99.4
EQ-5D-3L/EQ-5D-5L VAS values	100	99.4
SF-6D (via SF-12) values	98.2	99.4
6 months post randomisation		
Hospital inpatient care	83.0	78
Hospital outpatient attendances	82.5	78
Community health-care services	82.5	79.1
Social care services	83.0	79.1
Medications	82.5	78.5
Aids and adaptations	81.9	77.6
Additional (indirect) costs	84.2	81.4
Benefit payments	84.2	81.4
EQ-5D-3L/EQ-5D-5L utility values	82.5	82.5
EQ-5D-3L/EQ-5D-5L VAS values	90.6	94.9
SF-6D (via SF-12) values	85.4	79.7
12 months post randomisation		
Hospital inpatient care	85.5	76.3
Hospital outpatients attendances	84.2	76.3
Community health-care services	84.8	75.1
Social care services	84.2	74.6
Medications	84.2	75.1
Aids and adaptations	82.5	73.4
Additional (indirect) costs	86.5	78.0
Benefit payments	86.5	78.0
EQ-5D-3L/EQ-5D-5L utility values	88.3	82.5
EQ-5D-3L/EQ-5D-5L VAS values	95.3	89.3
SF-6D (via SF-12) values	84.8	74.6

TABLE 29 Summary of PHT attendance and costs by type of consultation, impingement and missed appointments

Attendance/consultation type	*n* (%)[a]	Mean (SE)		
		Number of consultations	Duration (minutes)	Total cost (£)[b]
Overall attendance				
Did not receive intervention	11 (6.2)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Offered one or more appointments (excluding DNAs)	166 (93.8)	7.31 (0.22)	220.87 (6.45)	192.16 (5.62)
Attended one or more sessions (excluding DNAs)	166 (93.8)	5.99 (0.21)	178.17 (6.04)	155.01 (5.25)
Offered six or more appointments (excluding DNAs)	110 (62.1)	7.74 (0.17)	225.93 (5.24)	196.56 (4.56)
Attended six or more sessions (excluding DNAs)	105 (59.3)	7.68 (0.15)	222.59 (4.81)	193.65 (4.18)
Attendance by type of consultation				
Face to face	160 (90.4)	5.66 (0.21)	170.94 (6.02)	148.71 (5.23)
Telephone	27 (15.3)	1.15 (0.07)	13.65 (1.56)	11.88 (1.35)
E-mail	4 (2.3)	1.00 (0.00)	27.70 (9.66)	24.10 (8.41)
Unknown	22 (12.4)	2.00 (0.35)	65.37 (11.76)	56.87 (10.23)
Attendance by type of impingement				
Cam	129 (72.9)	3.68 (0.18)	110.51 (5.47)	96.15 (4.76)
Pincer	13 (7.3)	4.96 (0.64)	151.64 (19.06)	131.93 (16.58)
Mixed	28 (15.8)	3.48 (0.38)	106.95 (12.04)	93.05 (10.48)
Missed appointments (i.e. DNA), total				
Attended at least one consultation	94 (53.1)	2.34 (0.19)	75.41 (6.28)	65.60 (5.46)
Attended at least six consultations	6 (3.4)	7.50 (0.85)	246.75 (27.85)	214.67 (24.23)
Missed appointments by type of consultation				
Face to face	3 (1.7)	1.00 (0.00)	26.67 (3.33)	23.20 (2.90)
Telephone	5 (2.8)	1.20 (0.20)	13.24 (1.83)	11.52 (1.59)
E-mail	1 (0.6)	1.00 (n/a)	32.90 (–)	28.62 (–)
Unknown	96 (54.2)	2.24 (0.19)	73.68 (6.16)	64.10 (5.36)
Attendance by recruitment site				
University Hospitals Coventry and Warwickshire	33 (18.6)	7.09 (0.48)	25.81 (0.77)	152.90 (8.97)
Yeovil District Hospital	8 (4.5)	3.50 (0.96)	36.88 (3.55)	104.34 (27.03)
Royal Devon and Exeter Hospital	8 (4.5)	6.62 (0.65)	30.72 (1.48)	180.53 (22.96)
Royal Orthopaedic Hospital	14 (7.9)	6.93 (0.71)	25.64 (1.23)	148.20 (14.66)
Frimley Park Hospital	4 (2.3)	6.25 (1.75)	31.72 (1.18)	175.09 (50.18)
Royal Cornwall Hospital	3 (1.7)	4.33 (0.88)	33.57 (1.99)	126.50 (25.19)
Elective Orthopaedic Centre (Epsom General Hospital)	1 (0.6)	6.00 (–)	23.33 (–)	121.80 (–)
Guy's and St Thomas' Hospital	7 (4.0)	7.00 (1.02)	33.37 (1.40)	206.18 (31.91)
Barts Health NHS Trust	3 (1.7)	5.33 (1.67)	33.95 (2.64)	150.28 (41.57)
University College Hospital	7 (4.0)	7.43 (0.95)	34.83 (0.82)	223.71 (27.93)
Wrightington Hospital	5 (2.8)	6.40 (1.12)	34.70 (1.37)	190.20 (30.82)
Northumbria Healthcare NHS Foundation Trust	9 (5.1)	5.22 (0.68)	32.49 (1.86)	140.45 (16.53)
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust	11 (6.2)	6.27 (0.70)	29.85 (0.29)	162.84 (18.34)

continued

TABLE 29 Summary of PHT attendance and costs by type of consultation, impingement and missed appointments (*continued*)

Attendance/consultation type	*n* (%)[a]	Mean (SE)		
		Number of consultations	Duration (minutes)	Total cost (£)[b]
Royal National Orthopaedic Hospital	3 (1.7)	7.67 (0.33)	32.68 (0.80)	217.50 (4.35)
The Robert Jones and Agnes Hunt Orthopaedic Hospital	3 (1.7)	8.00 (0.00)	31.67 (1.10)	220.40 (7.67)
South Tees Hospitals NHS Foundation Trust	4 (2.3)	7.00 (1.08)	30.17 (0.81)	181.96 (25.87)
University Hospital Llandough	2 (1.1)	3.50 (1.50)	47.25 (5.25)	137.02 (45.67)
Glasgow Royal Infirmary	2 (1.1)	9.50 (0.50)	34.11 (1.89)	282.75 (30.45)
Wrexham Maelor Hospital	2 (1.1)	7.00 (1.00)	31.72 (0.88)	193.93 (32.98)
King's College Hospital	4 (2.3)	5.25 (0.48)	36.15 (1.46)	163.93 (12.54)
North Bristol NHS Trust	4 (2.3)	6.75 (0.48)	27.75 (1.89)	162.04 (11.42)
Spire Healthcare (London, UK)	1 (0.6)	6.00 (–)	40.00 (–)	208.80 (–)
Recruitment site (missed appointments)				
University Hospitals Coventry and Warwickshire	7 (4.0)	3.00 (1.36)	32.90 (0.00)	85.87 (39.01)
Yeovil District Hospital	1 (0.6)	5.00 (–)	32.90 (–)	143.11 (–)
Royal Devon and Exeter Hospital	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Royal Orthopaedic Hospital	4 (2.3)	4.00 (1.78)	31.29 (1.61)	111.69 (52.05)
Frimley Park Hospital	2 (1.1)	2.50 (0.50)	18.95 (13.95)	47.29 (38.59)
Royal Cornwall Hospital	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Elective Orthopaedic Centre (Epsom General Hospital)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Guy's and St Thomas' Hospital	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Barts Health NHS Trust	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
University College Hospital	1 (0.6)	5.00 (–)	32.90 (–)	143.11 (–)
Wrightington Hospital	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Northumbria Healthcare NHS Foundation Trust	2 (1.1)	4.50 (0.50)	32.90 (0.00)	128.80 (14.31)
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust	3 (1.7)	3.00 (0.00)	32.90 (0.00)	85.87 (0.00)
Royal National Orthopaedic Hospital	1 (0.6)	1.00 (–)	32.90 (–)	28.62 (–)
The Robert Jones and Agnes Hunt Orthopaedic Hospital (AJ and RH)	1 (0.6)	7.00 (–)	32.90 (–)	200.36 (–)
South Tees Hospitals NHS Foundation Trust	1 (0.6)	2.00 (–)	32.90 (–)	57.25 (–)
University Hospital Llandough	4 (2.3)	2.00 (0.71)	32.90 (0.00)	57.24 (20.24)
Glasgow Royal Infirmary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wrexham Maelor Hospital	1 (0.6)	1.00 (–)	32.90 (–)	28.62 (–)
King's College Hospital	2 (1.1)	2.00 (0.00)	32.17 (0.72)	55.98 (1.27)
North Bristol NHS Trust	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spire Healthcare	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

–, was not possible to estimate the SE of relevant costs because of the small number of participants; DNA, did not attend; n/a, not applicable.

a Number of patients [as a percentage of the number of patients in PHT arm ($n = 177$)].

b Cost per minute of hospital physiotherapy (band 7), including qualifications and overheads (£0.87) (PSSRU 2016 section 13[52]).

micro-costing of the surgery sample was 34 (range 18–54) years, 60% were male and 68% had the cam impingement type. Compared with participants in the surgery arm of the trial and who were not included in the micro-costing sample (*Table 30*), those patients included were, on average, 2 years younger (mean age 34 vs. 35 years; $p = 0.405$), as likely to be male (60% vs. 58% male; $p = 0.997$) and had similar presentation with respect to type of impingement (68% vs. 78% cam; $p = 0.118$).

Estimates of resource use associated with the surgery and sources of unit cost data for resource inputs are presented in *Appendix 3*, *Table 34* and *Table 48*, respectively. Resource categories included operating theatre use/time, clinical staff, anaesthetic drugs, disposable surgical equipment and implants, and inpatient length of stay for post-surgical recuperation. The mean duration of surgery was 2.12 (range 1–3) hours and the mean length of inpatient stay was 1.6 (range 1–3) days (see *Appendix 3*, *Table 42*). The composition of the surgical team/staff remained broadly similar across centres and consisted of two surgeons (a consultant and an assistant or registrar), one anaesthetist, a radiographer, one or two nurses, two operating department practitioners and a health-care assistant.

Unit costs of clinical staff time were obtained from the PSSRU *Unit Costs of Health and Social Care 2016*[52] services and ranged from £28 per hour for a health-care assistant to £137 per hour for consultant surgeon (including qualifications and overheads). The running cost of an operating theatre was estimated based on data published by the Information Services Scotland.[54] The Information Services Scotland data showed that a total of £157,150,194.90 was allocated to operating theatres across Scotland for the 2015–16 financial year. The total number of theatre hour use recorded for the same period was 526,145.14 hours, generating a running cost of £298.68 per hour (see *Appendix 3*, *Table 42*). Allocated costs included non-clinical staff costs, property and equipment maintenance, domestics and cleaning, heating, lighting and power, and capital charges (e.g. the purchase of new equipment).[55] Equivalent data on the running costs of operating theatres in England and Wales were not publicly available and so only the Scottish data were used in our cost calculations. An inpatient stay was assumed to cost £332.77 per day, which is the excess bed-day cost for elective orthopaedics procedures in the 2016 reference costs schedules.[77] The unit costs of anaesthetic drugs were obtained from prescription cost analysis database,[53] electronic searches of the BNF[58] and searches of the literature, when necessary. Unit cost of syringes and needles and other medical consumables were obtained from online sources when more direct NHS sources were unavailable (see *Appendix 3*, *Table 42*).

TABLE 30 Summary characteristics of patients in the surgery arm of the trial by whether or not they were included in the surgery micro-costing study

	Included in surgery costing study		
Characteristic	**Yes ($N = 40$)**	**No ($N = 132$)**	***p*-value**
Age (years)			
Mean (SD)	34 (10)	36 (10)	0.405
Median (IQR)	32 (27–43)	36 (29–42)	
Sex, *n* (%)			
Female	16 (40)	55 (42)	0.997
Male	24 (60)	77 (58)	
Impingement type, *n* (%)			
Cam	27 (68)	103 (78)	0.118
Mixed	7 (18)	22 (17)	
Pincer	6 (15)	7 (5)	

IQR, interquartile range.

The quantity and unit costs of disposal equipment and implants such as blades, shavers, burrs and sutures used during surgery are presented in *Appendix 3*, *Table 44*. The cost of implements ranged from £35 per item for a Smith & Nephew-supplied banana blade (Smith & Nephew, London, UK) to £349.32 per item for a TAC-S radio-frequency probe (Smith & Nephew), and were primarily extracted from the NHS supply chain catalogue held within hospital finance and procurement departments.[56]

Cost estimates for the surgery resource use are summarised in *Table 31* by resource category and recruitment centre. The mean cost for the surgery ranged from £2286 per patient at North Bristol

TABLE 31 Costs associated with the delivery of hip arthroscopy by resource category and study centre

	Mean cost (£) (SE)					
Centre (number of patients)	Equipment	Staff	Theatre running costs	Anaesthetic drugs and disposables	Inpatient stay	Total
University Hospitals Coventry and Warwickshire ($n = 7$)	1083 (155)	1154 (96)	626 (45)	122 (0)	711 (0)	3695 (202)
Yeovil District Hospital ($n = 2$)	458 (32)	1119 (172)	571 (86)	122 (0)	711 (0)	2980 (290)
Royal Devon and Exeter Hospital ($n = 1$)	495 (–)	845 (–)	606 (–)	122 (–)	711 (–)	2779 (–)
Royal Orthopaedic Hospital ($n = 0$)[a]	–	–	–	–	–	–
Frimley Park Hospital ($n = 1$)	502 (–)	558 (–)	358 (–)	122 (–)	355 (–)	1895 (–)
Guy's and St Thomas' Hospital ($n = 1$)	657 (–)	1244 (–)	728 (–)	122 (–)	355 (–)	3105 (–)
University College Hospital ($n = 3$)	902 (305)	1197 (180)	674 (96)	122 (0)	592 (118)	3487 (506)
Wrightington Hospital ($n = 3$)	856 (221)	1260 (74)	749 (40)	122 (0)	355 (0)	3343 (200)
Northumbria Healthcare NHS Foundation Trust ($n = 2$)	685 (7)	958 (404)	515 (157)	122 (0)	355 (0)	2634 (567)
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust ($n = 6$)	522 (122)	1058 (126)	564 (61)	122 (0)	533 (79)	2798 (256)
Royal National Orthopaedic Hospital ($n = 1$)	734 (–)	1556 (–)	598 (–)	122 (–)	1066 (–)	4076 (–)
The Robert Jones and Agnes Hunt Orthopaedic Hospital (AJ and RH) ($n = 1$)	1014 (–)	1097 (–)	753 (–)	122 (–)	711 (–)	3697 (–)
South Tees Hospitals NHS Foundation Trust ($n = 2$)	925 (380)	1172 (78)	587 (0)	122 (0)	355 (0)	3161 (458)
University Hospital Llandough ($n = 1$)	563 (98)	970 (77)	564 (32)	122 (0)	355 (0)	2574 (200)
Wrexham Maelor Hospital ($n = 1$)	446 (–)	1446 (–)	846 (–)	122 (–)	711 (–)	3570 (–)
King's College Hospital ($n = 2$)[a]	–	–	–	–	–	–
North Bristol NHS Trust ($n = 4$)	429 (145)	827 (154)	465 (76)	122 (0)	444 (89)	2286 (448)
Spire ($n = 1$)	843 (–)	455 (–)	282 (–)	122 (–)	711 (–)	2412 (–)
Spire Healthcare ($n = 40$)	719 (58)	1067 (47)	591 (23)	122 (0)	542 (31)	3042 (116)

–, was not possible to estimate the SE of relevant costs because of the small number of participants.
a Excluded questionnaires from these centres because of missing duration of surgery data or missing post-surgery inpatient length of stay data.

NHS Trust to £4076 per patient at the Royal National Orthopaedic Hospital. Across all the centres, the overall mean cost was £3042, 35.3% of which was staffing costs, 23.5% disposal surgical equipment and implants, 19.4% theatre running costs, 17.8% inpatient costs and 4% represent the cost of anaesthesia, including drugs, syringes and needles. These figures represent estimates associated with delivery of hip arthroscopy and do not account for pre- and post-surgery consultations, diagnostic scans and post-surgical rehabilitation costs. These additional costs were, however, taken into account in the cost-effectiveness analysis as follow-up costs if they were reported by trial participants at the 6- and 12-month assessment points.

Follow-up resource use and costs

Descriptive summaries of self-reported health and social care service use are presented in *Appendix 3*, *Table 45*, by assessment point, resource category and treatment group. The proportion of missing data across all categories of resource inputs ranged from 1.2% at baseline to 17.5% at 12 months post randomisation in the surgery group and from 0.6% at baseline to 26.6% at 12 months post randomisation in the PHT group. Across the majority of resource categories, the baseline values displayed in *Appendix 3*, *Table 45*, suggest no more than 8.2% and 10.7% of the patients in surgery and PHT groups, respectively, reported use of health and social care services in the 3-month period prior to randomisation. The only exceptions were GP attendance, medication use and orthopaedic outpatient attendance in the same period. Slightly over one-third of patients (36% in the surgery group and 41% in the PHT group) reported attending at least one GP consultation, with a similar proportion of patients reporting being prescribed medication and 57% attending an orthopaedic outpatient appointment. Overall, the treatment groups were generally balanced with respect to reported resource use across all categories of health and social care services at baseline.

Rates of service use over 12 months of follow-up were also broadly similar between the two treatment groups for most resource categories. However, at the 6-month assessment point, the surgery group reported, on average, 0.035 (95% CI 0.011 to 0.118; $p = 0.038$) more inpatient hospitalisation days for the category 'other inpatient admissions', 0.362 (95% CI 0.116 to 1.032; $p = 0.016$) more orthopaedic outpatient consultations, 0.499 (95% CI 0.224 to 1.588; $p = 0.002$) more outpatient physiotherapy attendance for the category 'your hip/leg', and significant use of prescribed medication, walking aids and adaptations, than the PHT group. At the 12-month assessment point, the surgery group also reported, on average, 0.596 (95% CI 0.089 to 2.544; $p = 0.002$) more inpatient days, 0.041 (95% CI 0.007 to 0.129; $p = 0.030$) more day case admissions and 1.789 (95% CI 1.379 to 4.554; $p < 0.001$) more outpatient physiotherapy attendances than the PHT group. Compared with the PHT group, attendance rates at outpatient orthopaedic and physiotherapy clinics were also higher among the surgery group at 12 months post randomisation, as were the use of clutches, dressing aids and number of prescriptions received.

Unit cost of resource inputs together with corresponding sources of unit costs are presented in *Appendix 3*, *Table 46*. *Appendix 3*, *Table 47*, presents health and social service costs generated by assigning the unit cost data to resource inputs summarised by resource category, treatment group and assessment point. The mean total cost across all categories of resource use at baseline, covering the 3-month period prior to randomisation, was £502.12 in the surgery group and £508.53 in the PHT group, generating an unadjusted mean total cost difference of –£6.41 (95% CI –£235.01 to £246.59; $p = 0.880$). Total cost across all resource categories based on the 6- and 12-month data was generally higher in the surgery group than in the PHT group, but the unadjusted between-group difference in costs was only statistically significant at the 6-month assessment point. Over the 12 months of follow-up, the mean total cost was £1640.91 in the surgery group and £941.02 in the PHT group, generating a statistically significant unadjusted cost difference of £699.88 (95% CI £274.36 to £1121.23; $p < 0.001$).

Private health expenditure, lost income and other costs

Private health-care service use and related out-of-pocket expenses by patients, friends and family members in the 3-month period prior to randomisation and the 12-month post-randomisation period are summarised in *Appendix 3*, *Tables 48* and *49*, respectively. The proportion of missing data across all categories of resource inputs ranged from 1.2% at baseline to 18.1% and 17.5% at 6 and 12 months post randomisation, respectively, in the surgery group and from 0.6% at baseline to 26.6% at 12 months post randomisation in the PHT group. Private health-care services included private physiotherapy consultations, purchase of over-the-counter medication and purchase of walking aids, such as crutches, sticks and specialised shoes. There was no statistically significant difference between the two treatment groups across all categories of private health-care utilisation at baseline and over the 12 months of follow-up (see *Appendix 3*, *Table 48*). The mean cost of private health utilisation in the 3-month period prior to randomisation (baseline figures) was £10.89 in the surgery group and £14.95 in the PHT group, generating an unadjusted cost difference of −£4.06 (95% CI −£25.07 to £11.16; $p = 0.760$) (see *Appendix 3*, *Table 49*). Over the 12 months of follow-up, private health-care and out-of-pocket expenditure increased from the baseline figures to about £32.67, on average, in the surgery group and £27.44 in the PHT group, generating a mean cost difference of £5.23 (95% CI −£23.55 to £32.41; $p = 0.704$).

Appendix 3, *Table 46*, presents a summary of additional (indirect or non-health service) costs, for example the value of lost income incurred by patients and their families for the 3-month period prior to randomisation (baseline figures) and over the 12-month period of follow-up. Only costs incurred as a result of inability to work or perform tasks because of their hip pain were included in these additional (indirect) cost calculations. These costs included lost earnings, help with house work, child care and expenditure on specialised equipment. The mean additional cost reported by patients for the 3-month period prior to randomisation was £164.15 in the surgery group and £111.49 in the PHT group, generating a mean additional cost difference of £52.66 (95% CI −£189.36 to £470.01; $p = 0.748$). Over the 12 months of follow-up, the corresponding costs reported increased to £1143.20 in the surgery group and to £184.81 in the PHT group, generating a cost difference of £958.39 (95% CI £219.74 to £2001.32; $p = 0.004$). Lost income accounted for approximately 92% of the additional costs in the surgery group, but only 60% of additional costs in the PHT group at baseline. Over the 12 months of follow-up, lost income accounted for approximately 83% and 76% of the additional costs in the surgery and PHT groups, respectively.

Total economic costs

Table 32 summarises the total costs during the 12-month follow-up period by treatment group, cost category and cost perspective. Among the complete cases, the mean total cost from a NHS and Personal Social Service Perspective was £3712.77 in the surgery group and £1282.93 in the PHT group, generating an unadjusted cost difference of £2429.84 (95% CI £1865.92 to £2911.70; $p < 0.001$). Surgery costs accounted for approximately 72% of total costs in the surgery group, whereas the treatment costs (including surgery costs for PHT patients who had surgery) accounted for only 28% of the overall costs in the PHT group. The corresponding mean total cost estimated from a societal perspective was £4993.84 in the surgery group, of which 53.5% was surgery costs, and £1481.96 in the PHT group, of which 24% was accounted for by treatment costs, generating an unadjusted cost difference of £3511.88 (95% CI £2490.57 to £4784.53; $p < 0.001$).

Benefit payments

Patient self-reports of benefit payments, pensions and statutory sick pay are presented in *Appendix 3*, *Table 51*. The proportion of patients with missing data on benefit payments ranged from 2.3% at baseline to 17% and 14% at the 6- and 12-month assessment points, respectively, in the surgery group and from 0.6% at baseline to 20.3% and 22% at 6 and 12 months post randomisation in the PHT group. Examples of benefit payments that were reported during follow-up include Attendance Allowance,

TABLE 32 Total economic costs

Costing perspective	Treatment group: Surgery ($n = 171$) % missing	Surgery ($n = 171$) % zero costs	Surgery ($n = 171$) Mean (£) (SE)	PHT ($n = 177$) % missing	PHT ($n = 177$) % zero costs	PHT ($n = 177$) Mean (£) (SE)	Surgery vs. PHT: Mean difference (£) (bootstrap 95% CI)[a]	Surgery vs. PHT: *p*-value[b]
NHS/Personal Social Services perspective								
Treatment costs	1.2	15.8	2673.57 (83.52)	0.0	0.0	352.88 (81.61)	2320.69 (2101.32 to 2550.03)	< 0.001
Follow-up costs	33.3	5.3	884.53 (149.28)	40.7	7.3	950.64 (155.54)	−66.11 (−555.66 to 334.16)	0.818
Total NHS/Personal Social Services costs	33.3	1.2	3712.77 (177.02)	40.7	0.0	1282.93 (184.45)	2429.84 (1865.92 to 2911.70)	< 0.001
Societal perspective								
Treatment costs	1.2	15.8	2673.57 (83.52)	0.0	0.0	352.88 (81.61)	2320.69 (2096.77 to 2546.05)	< 0.001
Follow-up costs (NHS/Personal Social Services)	33.3	5.3	884.53 (149.28)	40.7	7.3	950.64 (155.54)	−66.11 (−547.32 to 338.69)	0.844
Follow-up costs (non-NHS/Personal Social Services)	33.3	19.9	1281.08 (376.1)	40.7	22.6	199.03 (391.89)	1082.04 (233.70 to 2236.23)	0.002
Total societal costs	33.3	1.2	4993.84 (418.83)	40.7	0.0	1481.96 (436.41)	3511.88 (2490.57 to 4784.53)	< 0.001

a CIs obtained by bootstrap percentile method.
b Two-sided *p*-values obtained by counting the proportion of bootstrap replicates in which the mean cost difference is positive, multiplied by 2 and taking a minimum.

Income Support, Housing Benefit, Carer's Allowance, Child Tax Credit, Council Tax Reduction, Employment and Support Allowance, and Disability Living Allowance. The proportion of patients in receipt of at least one of these payments increased from 10.6% at baseline to 17.6% over the 12 months of follow-up in the surgery group, but decreased in the PHT group from 6.2% at baseline to 5.7% over the 12 months of follow-up. The average reported payment per patient at baseline was £17.62 in the surgery group and £11.90 in the PHT group, generating a between-group difference of £5.72 (95% CI −£20.89 to £36.78; $p = 0.512$) in the 3-month period prior to randomisation. Over the 12 months of follow-up, receipts increased from baseline values to £57.93 in the surgery group and £12.94 in the PHT group, generating an unadjusted mean difference of £44.99 (95% CI £10.88 to £97.42; $p < 0.001$).

Health-related quality of life

Of the 351 patients randomised, the first 97 patients who were recruited into the feasibility study sample completed the EQ-5D-3L questionnaire, whereas the remaining 251 patients were recruited into the main study sample and completed the EQ-5D-5L questionnaire. In addition, health-related quality-of-life data were collected for both feasibility and main trial samples using version 2 of the SF-12 questionnaire. *Appendix 3*, *Tables 52–54*, present descriptive summaries of the responses to these questionnaires by treatment group and assessment point. Treatment groups were balanced with respect to function (i.e. optimal vs. suboptimal response to each health dimension) at baseline and there were no statistically significant differences between the two groups in the distribution of responses across all health dimensions and assessment points.

The utility weights generated from the EQ-5D-3L/EQ-5D-5L and the SF-6D (via the SF-12) are summarised in *Table 33* by questionnaire instrument, assessment point and treatment group. The proportion of missing data ranged from 0% at baseline to no more than 20% and 15% at the 6- and 12-month assessment points, respectively, in the surgery group and from 0% to no more than 21.4% and 25.5% at the 6- and 12- month assessment points, respectively, in the PHT group. On average, patients in the surgery group had higher utility scores at baseline based on the responses to the EQ-5D-5L and lower scores based on the responses to the EQ-5D-3L and the SF-12, but between-group differences in baseline scores were not statistically significant for all measures. Among patients with complete data, the mean unadjusted utilities generated from the EQ-5D-3L/EQ-5D-5L increased from 0.58 at baseline to 0.59 and 0.67 at 6 and 12 months post randomisation, respectively, in the surgery group and from 0.56 at baseline to 0.62 at both 6 and 12 months post randomisation in the PHT group. The corresponding utility values generated from the SF-6D UK tariff increased from 0.64 at baseline to 0.65 and 0.69 at 6 and 12 months post randomisation, respectively, in the surgery group and from 0.64 at baseline to 0.66 and 0.68 at 6 and 12 months post randomisation, respectively, in the PHT group.[46] There was no statistically significant between-group difference at baseline across all quality-of-life measures, but the surgery group, on average, reported worse EQ-5D-3L/EQ-5D-5L utility scores at 6 months (unadjusted mean difference −0.012, 95% CI −0.04 to 0.015) and improved scores at 12 months after randomisation (unadjusted mean difference 0.049, 95% CI −0.01 to 0.108; $p = 0.105$) (see *Table 33*).

QALY values were generated from combining health-related quality of life weights (measured at baseline and at 6 and 12 months post randomisation) over the 12 months of follow-up using area-under-the-curve approaches (see *Table 35*). Mean QALYs based on the combined EQ-5D-3L/EQ-5D-5L utility score were 0.617 in the surgery group and 0.613 in the PHT, generating an unadjusted difference of 0.005 (−0.046 to 0.055, p-value = 0.859) QALYs over the 12 months of follow-up. Unadjusted QALY differences between the surgery and PHT groups generated for the feasibility and the main trial population when variants of the EQ-5D measure were applied, and separately for the whole trial population when SF-6D utility values were applied, were not statistically significant.

TABLE 33 Summary of health utility scores generated from patient-reported health-related quality-of-life measures at baseline and at 6 and 12 months post randomisation

	Treatment group							
	Surgery			PHT			Surgery vs. PHT	
Outcome	*n*	% missing	Mean (SE)	*n*	% missing	Mean (SE)	Mean difference (95% CI)	*p*-value
EQ-5D-3L/EQ-5D-5L crosswalk[a]								
Baseline	171	1.8	0.575 (0.02)	177	0.6	0.557 (0.019)	0.018 (−0.035 to 0.072)	0.5
6 months	171	17.5	0.586 (0.022)	177	17.5	0.617 (0.022)	−0.031 (−0.092 to 0.031)	0.33
12 months	171	11.7	0.671 (0.021)	177	17.5	0.622 (0.021)	0.049 (−0.01 to 0.108)	0.105
SF-12 (SF-6D UK tariff)								
Baseline	171	1.8	0.639 (0.009)	177	0.6	0.642 (0.009)	−0.003 (−0.028 to 0.021)	0.797
6 months	171	14.6	0.648 (0.01)	177	20.3	0.659 (0.01)	−0.011 (−0.04 to 0.017)	0.421
12 months	171	15.2	0.69 (0.01)	177	25.4	0.683 (0.011)	0.007 (−0.023 to 0.037)	0.644
EQ-5D-3L								
Baseline	46	4.3	0.529 (0.046)	51	2.0	0.555 (0.044)	−0.026 (−0.153 to 0.1)	0.68
6 months	46	10.9	0.602 (0.049)	51	9.8	0.611 (0.046)	−0.008 (−0.142 to 0.125)	0.9
12 months	46	15.2	0.621 (0.052)	51	23.5	0.664 (0.052)	−0.043 (−0.189 to 0.103)	0.558
EQ-5D-5L (crosswalk tariff)								
Baseline	125	0.8	0.591 (0.021)	126	0.0	0.557 (0.02)	0.034 (−0.023 to 0.091)	0.239
6 months	125	20.0	0.579 (0.024)	126	20.6	0.619 (0.024)	−0.04 (−0.108 to 0.028)	0.247
12 months	125	10.4	0.688 (0.022)	126	15.1	0.606 (0.022)	0.082 (0.02 to 0.143)	0.01
EQ-5D-5L (new UK tariff)								
Baseline	125	0.8	0.7 (0.02)	126	0.0	0.669 (0.019)	0.031 (−0.023 to 0.085)	0.262
6 months	125	20.0	0.691 (0.022)	126	20.6	0.724 (0.022)	−0.033 (−0.096 to 0.029)	0.294
12 months	125	10.4	0.782 (0.021)	126	15.1	0.702 (0.022)	0.08 (0.02 to 0.139)	0.009

continued

TABLE 33 Summary of health utility scores generated from patient-reported health-related quality-of-life measures at baseline and at 6 and 12 months post randomisation (*continued*)

	Treatment group							
	Surgery			PHT			Surgery vs. PHT	
Outcome	*n*	% missing	Mean (SE)	*n*	% missing	Mean (SE)	Mean difference (95% CI)	*p*-value
EQ-5D-3L VAS								
Baseline	46	0.0	61.587 (3.037)	51	2.0	68.9 (2.913)	−7.313 (−15.668 to 1.042)	0.086
6 months	46	6.5	64.302 (3.339)	51	9.8	68.022 (3.228)	−3.719 (−12.95 to 5.511)	0.425
12 months	46	13.0	67.375 (3.391)	51	15.7	70.953 (3.27)	−3.578 (−12.952 to 5.795)	0.45
EQ-5D-5L VAS								
Baseline	125	0.0	69.168 (1.685)	126	0.0	66.556 (1.678)	2.612 (−2.071 to 7.296)	0.273
6 months	125	18.4	69.324 (1.787)	126	21.4	71.323 (1.813)	−2 (−7.02 to 3.02)	0.433
12 months	125	12.0	73.545 (1.857)	126	19.0	68.402 (1.928)	5.143 (−0.134 to 10.421)	0.056

a EQ-5D-3L was used in the feasibility study and EQ-5D-5L in the main trial. The EQ-5D-5L utility values were derived using the interim EQ-5D-5L to EQ-5D-3L crosswalk tariffs for the UK published by EuroQoL foundation (https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/; accessed 16 December 2021).

Cost-effectiveness results

Base-case analysis results

Table 34 presents estimates of the cost-effectiveness of hip arthroscopy compared with PHT for FAI. In the base-case analysis, surgery was associated with an adjusted mean additional cost of £2483 (95% CI £1533 to £3432) and an adjusted mean additional QALY of −0.018 (95% CI −0.051 to 0.015) per patient compared with PHT over the 12 months of follow-up. On average, surgery was more costly and marginally less effective than PHT in the adjusted analysis during the first year of follow-up. The mean base-case ICER was −£140,361 per QALY gained for surgery compared with PHT. *Figure 14* shows the uncertainty around this central estimate of the ICER. *Figure 14a* displays 1000 simulated replicates of the ICER on a cost-effectiveness plane and *Figure 14b* displays the probability that surgery is cost-effective compared with PHT for a range of cost-effectiveness thresholds. Almost all simulated replicates of the ICER fell on the left-hand side of the £30,000 and £50,000 per QALY cost-effectiveness threshold lines, with the central estimate (indicated by the black diamond) falling in the north-west quadrant. This suggests that surgery is unlikely to be cost-effective at the £20,000–£30,000 per QALY threshold range (see *Figure 14b*) that NICE currently uses to determine the cost-effectiveness of health technologies.[67] *Figure 14b* shows that the probability that surgery is cost-effective compared with PHT is close to zero for threshold values < £100, 0000 per QALY.

Mean incremental net (monetary) benefit was also generated from the 1-year data for different cost-effectiveness thresholds (*Table 35*). The mean incremental net benefit was −£2713 if the cost-effectiveness threshold was £13,000 per QALY gained, −£3013 if the cost-effectiveness threshold was £30,000 per QALY gained and −£3367 if the cost-effectiveness threshold was £50,000 per QALY gained. These values (and the associated upper and lower 95% CI confidence limits) are all negative and suggest a net loss to the health and social care service based on the 1-year data if surgery is adopted (or a net gain by the same amount, on average, if PHT is adopted).

Sensitivity analyses results

Only the unadjusted analysis generated a difference in mean QALYs of 0.001 in favour of the surgery. The probability that surgery is cost-effective was 0.005 at £30,000 per QALY and no more than 0.05 at £50,000 per QALY (see *Table 34*). All other sensitivity analyses adjusted for baseline characteristics, such as age, sex, impingement type, study site, health-care service use prior to randomisation and health-related quality of life. In the adjusted sensitivity analyses, surgery was significantly more expensive (adjusted mean difference in costs ranged from £2047 to £5628) and generated fewer QALYs (adjusted mean difference in QALYs ranged from −0.018 to −0.003), on average, than PHT over 12 months of follow-up (see *Table 34*). Cost-effectiveness acceptability curves and plots of simulated ICERs, displayed in *Appendix 3*, *Figures 15–21*, for the different scenarios evaluated through the sensitivity analyses, show that surgery is unlikely to be cost-effective even at willingness-to-pay threshold values as high as £100,000 per QALY.

Subgroup analyses results

The subgroup analyses results are also summarised in *Tables 34* and *35* and displayed graphically in *Appendix 3*, *Figures 22–28*. There was substantial uncertainty around the central estimates of incremental costs and incremental QALYs because of the reduced sample size in each subgroup, but the direction of relative cost-effectiveness of the interventions remained mostly the same as in the base-case analysis. Across all subgroups of patients, surgery mostly generated fewer QALYs (adjusted mean difference in QALYs ranged from −0.019 to −0.006) and was significantly more expensive (adjusted mean difference in costs ranged from £2058 to £3260), on average, than PHT.

Long-term modelling

The study protocol had allowed for trial participants to be followed up beyond the initial 12-month period for up to 3 years and outcome data collected at the end of the second and third year post randomisation. Given that the 12-month within-trial economic analysis did not show evidence of

TABLE 34 Cost-effectiveness results for the within-trial economic analysis with a 1-year time horizon

Description	Cost-effectiveness outcome			Probability surgery is cost-effective at cost-effectiveness threshold of			
	Mean incremental costs (£) (95% CI)	Mean incremental QALYs (95% CI)	ICER[a]	£13,000/QALY	£20,000/QALY	£30,000/QALY	£50,000/QALY
Base-case analysis[b]	2483 (1533 to 3432)	−0.018 (−0.051 to 0.015)	−140,361	0	0	0	0
Sensitivity analyses							
Unadjusted analysis	2515 (1581 to 3450)	0.001 (−0.048 to 0.049)	4,196,009	0	0	0.005	0.05
Adjusted complete-case analysis	2425 (2043 to 2807)	−0.017 (−0.050 to 0.017)	−144,799	0	0	0	0
Per-protocol sample[c]	2689 (1627 to 3750)	−0.013 (−0.050 to 0.023)	−205,243	0	0	0	0
Per-protocol sample[d]							
Assume surgery costs are £2680[e]	2498 (1551 to 3444)	−0.018 (−0.052 to 0.016)	−136,562	0	0	0	0
Assume surgery costs are £5811[f]	5628 (4682 to 6575)	−0.018 (−0.052 to 0.016)	−307,703	0	0	0	0
Societal costs	3689 (2140 to 5238)	−0.023 (−0.056 to 0.010)	−160,577	0	0	0	0
SF-12/SF-6D	2431 (1500 to 3362)	−0.003 (−0.018 to 0.012)	−779,664	0	0	0	0
Subgroups							
Feasibility sample (EQ-5D-3L)	2234 (1567 to 2901)	−0.006 (−0.074 to 0.062)	−368,113	0	0	0.02	0.077
Main study sample (EQ-5D-5L crosswalk value set)	2614 (1245 to 3984)	−0.019 (−0.058 to 0.020)	−134,395	0	0	0	0.001
Main study sample (EQ-5D-5L new UK value set)	2719 (1225 to 4214)	−0.016 (−0.049 to 0.016)	−165,227	0	0	0	0.001
Impingement type: cam	2327 (1905 to 2749)	−0.006 (−0.042 to 0.029)	−359,783	0	0	0	0.002
Impingement type: pincer/mixed	2992 (−694 to 6679)	−0.020 (−0.101 to 0.061)	−149,445	0.062	0.062	0.073	0.1
Restricted analysis to women only	2047 (1248 to 2846)	−0.013 (−0.066 to 0.039)	−151,606	0	0	0.003	0.027
Restricted analysis to men only	2826 (1297 to 4354)	−0.012 (−0.053 to 0.029)	−241,044	0.002	0.003	0.005	0.013

a Mean ICERs for base-case, sensitivity and subgroup analyses all fell in the north-west quadrant of the cost-effectiveness plane, where surgery is more costly and less effective than PHT.
b Adjusted for age, sex, treatment allocation, study site, impingement type, baseline health-related quality of life and baseline costs.
c Per-protocol sample 1: restricted analysis to patients who received the allocated treatment arm intervention (i.e. excluded crossovers, surgery patients who did not have surgery and patients in the PHT arms who did not have PHT).
d Per-protocol sample 2.
e HRG code HT15Z (Minor Hip Procedures for Trauma, elective long-stay).
f HRG code HT12A [Very Major Hip Procedures for Trauma with CC Score 12 +(elective long stay)].

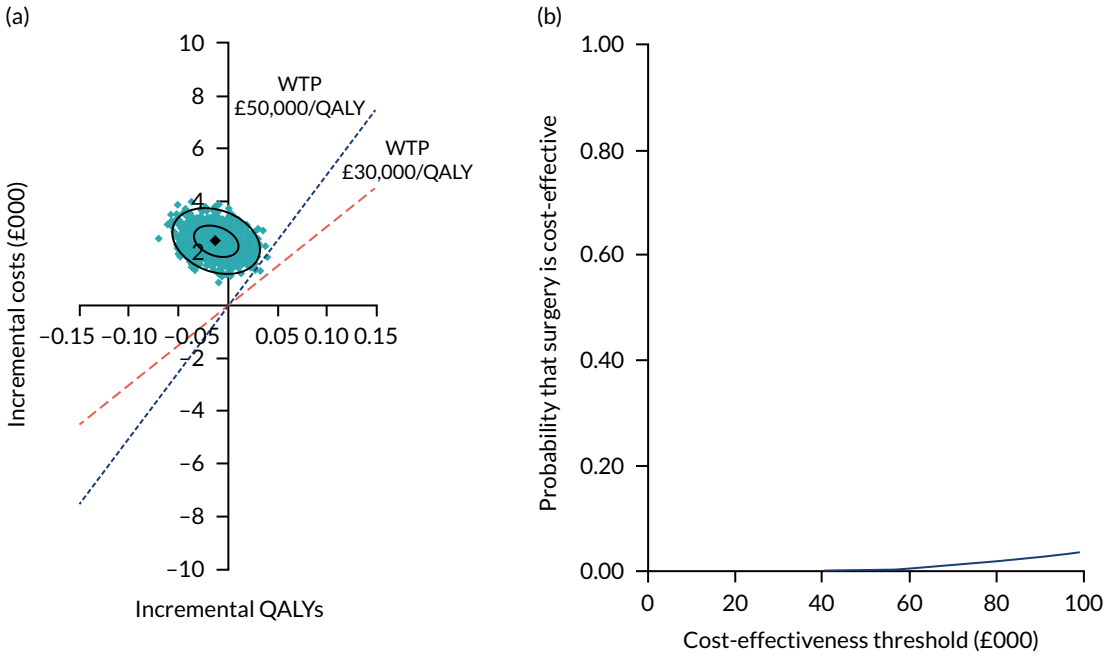

FIGURE 14 Base-case analysis comparing the cost-effectiveness of arthroscopic surgery with PHT for FAI. The analysis accounted for missing data using multiple imputation and adjusting for age, sex and baseline health-related quality of life (effectiveness regression). (a) Incremental costs; and (b) probability that surgery is cost-effectiveness. WTP, willingness to pay.

cost-effectiveness in favour of the surgery, it is doubtful if long-term economic modelling would be meaningful without this additional data. In addition, 11 patients representing 7.3% of the PHT group had crossed over and received surgery during the 12-month follow-up period. The net effect of patients crossing over to surgery may increase costs in the PHT arm and decrease the incremental costs between surgery and PHT. If more and more PHT patients continue to cross over to surgery in subsequent years, then they will be picked up at the second- and third-year assessments. Therefore, an assessment of the utility of a long-term economic model should be delayed until the second- and third-year data become available. This would provide a more accurate assessment of outcomes over a longer follow-up period and determine whether or not modelling is needed to capture the long-term (i.e. lifetime) costs and consequences of treatment.

TABLE 35 Incremental net (monetary) benefit of surgery compared with PHT for FAI at cost-effectiveness thresholds of £20,000, £30,000 and £50,000 per QALY gained

Description	Mean incremental net (monetary) benefit (£ 2016 prices) and 95% CIs at cost-effectiveness threshold of			
	£13,000/QALY	£20,000/QALY	£30,000/QALY	£50,000/QALY
Base-case analysis[a]	−2713 (−3842 to −1583)	−2836 (−4125 to −1548)	−3013 (−4566 to −1460)	−3367 (−5523 to −1211)
Sensitivity analyses				
Unadjusted analysis	−2507 (−3748 to −1267)	−2503 (−4012 to −994)	−2497 (−4441 to −554)	−2485 (−5375 to 405)
Adjusted complete-case analysis	−2642 (−3246 to −2038)	−2759 (−3561 to −1957)	−2927 (−4038 to −1816)	−3262 (−5023 to −1500)
Per-protocol sample[b]	−2859 (−4136 to −1582)	−2951 (−4378 to −1523)	−3082 (−4768 to −1396)	−3344 (−5632 to −1056)
Per-protocol sample[c]				
Assume surgery costs are £2680[d]	−2736 (−3869 to −1602)	−2864 (−4165 to −1562)	−3047 (−4624 to −1469)	−3412 (−5608 to −1216)
Assume surgery costs are £5811[e]	−5866 (−7000 to −4732)	−5994 (−7296 to −4692)	−6177 (−7755 to −4599)	−6543 (−8739 to −4347)
Societal costs	−3988 (−5678 to −2298)	−4148 (−5931 to −2366)	−4378 (−6332 to −2424)	−4838 (−7232 to −2443)
SF-12/SF-6D	−2472 (−3426 to −1517)	−2493 (−3479 to −1508)	−2525 (−3569 to −1480)	−2587 (−3791 to −1382)
Subgroups				
Feasibility sample (EQ-5D-3L)	−2313 (−3501 to −1125)	−2355 (−3972 to −739)	−2416 (−4683 to −150)	−2537 (−6148 to 1073)
Main study sample (EQ-5D-5L crosswalk value set)	−2867 (−4391 to −1343)	−3003 (−4668 to −1339)	−3198 (−5114 to −1282)	−3587 (−6115 to −1059)
Main study sample (EQ-5D-5L new UK value set)	−2933 (−4567 to −1300)	−3049 (−4794 to −1304)	−3213 (−5155 to −1272)	−3542 (−5966 to −1119)
Impingement type: cam	−2411 (−3079 to −1743)	−2456 (−3337 to −1576)	−2521 (−3736 to −1306)	−2651 (−4570 to −731)
Impingement type: pincer/mixed	−3253 (−7342 to 837)	−3393 (−7759 to 974)	−3593 (−8436 to 1250)	−3993 (−9989 to 2002)
Restricted analysis to women only	−2222 (−3284 to −1160)	−2317 (−3666 to −967)	−2452 (−4275 to −628)	−2722 (−5577 to 134)
Restricted analysis to men only	−2978 (−4748 to −1208)	−3060 (−4993 to −1128)	−3177 (−5390 to −965)	−3412 (−6287 to −537)

a Adjusted for age, sex, treatment allocation, impingement type, study site, baseline health-related quality of life and baseline costs.
b Per-protocol sample 1: restricted analysis to patients who received the allocated treatment arm intervention (i.e. excluded crossovers, surgery patients who did not have surgery and patients in the PHT arms who did not have PHT).
c Per-protocol sample 2.
d HRG code HT15Z (Minor Hip Procedures for Trauma, elective long-stay).
e HRG code HT12A [Very Major Hip Procedures for Trauma with CC Score 12 +(elective long stay)].

Chapter 6 Discussion

To the best of our knowledge, the UK FASHIoN trial is the first RCT evidence that hip arthroscopy with postoperative rehabilitation is effective in patients with FAI syndrome. In this pragmatic trial, after 12 months, there was a mean difference in iHOT-33 scores of 6.8 points in favour of patients allocated to hip arthroscopy, compared with those who were allocated to a best conservative care strategy of PHT. This is a statistically significant difference that exceeds the MCID for the iHOT-33. The results are consistent with the hypothesis that hip arthroscopy is more clinically effective than best conservative care.

There have been many observational studies showing benefit from hip arthroscopy; however, these studies generally did not have control groups for comparison and were at high risk of bias.[3] Our previous systematic review[16] showed that there had been no previous relevant RCTs. One RCT has recently reported no difference in outcome between hip arthroscopy and conservative care.[78] This study was small, conducted in a military setting, with a single surgeon in a single centre and with a very high rate of crossover (70%) from conservative care to hip arthroscopy.[78] When the authors performed a per-protocol comparison of those who had hip arthroscopy ($n = 66$) with those who had conservative care ($n = 14$), they reported that 'power was lost making type II errors possible'.[78] The authors concluded that 'large cohorts across multiple sites are needed to make definitive conclusions'.[78] This trial is much larger and, therefore, has greater power to detect between-group differences as statistically significant, and was conducted in 23 centres and in a more generalisable population.[78]

There was no difference in secondary outcome measures of general health-related quality of life (i.e. EQ-5D-5L and SF-12) between PHT and arthroscopic surgery. This could either be because treatment for FAI syndrome does not have an effect on health-related quality of life or because the measures are not sufficiently sensitive to detect the changes that occur. A further possibility is that the trial was not sufficiently powered to detect changes in health-related quality of life.

Complications in the hip arthroscopy group were more frequent than in the PHT group. However, there was only one serious surgical complication in which a patient developed a deep hip infection. Hip arthroscopy is considered relatively safe, with a reported minor complication rate of 7.9% and major complication rate of 0.45% in a large systematic review.[79] The UK FASHIoN trial results are consistent with this.[80] The delay in surgical treatment may have affected the collection of complication data; but most complications from surgery occur within the first 6 weeks and complications data were available for 138 of the 144 participants who received a hip arthroscopy compared with 146 of the 154 participants who received PHT. This suggests that the delay in treatment did not cause an under-reporting of complications.

The within-trial health economic evaluation suggests that hip arthroscopy is not cost-effective in comparison with PHT. However, our economic models were able to assess cost-effectiveness at only 12 months from randomisation. This must also be set in the context of the high initial treatment costs of hip arthroscopy, the treatment timing (i.e. a long delay in hip arthroscopy, reducing the period of potential benefit during follow-up), the period of economic inactivity during the period of postoperative recovery and subsequent hip arthroscopy in one-quarter of PHT patients in the first 3 years after randomisation. There may be longer-term differences between groups that were not assessed in this economic analysis, and further follow-up points at 5 and 10 years will inform the life time cost-effectiveness of both surgery and PHT. For example, hip replacement rates appear to have diverged at 3 years and the longer-term comparison of this rate between groups will help establish whether or not surgery affects the risk of osteoarthritis and consequent societal and health-care costs.[7,81]

The differences in the primary outcome reached statistical significance at 12 months and the mean value was greater than the MCID of the iHOT-33. However, the CIs overlap the MCID, raising the

possibility that hip arthroscopy is superior to PHT, but not to a clinically significant amount. These differences must be set in the context of other factors, such as the greater delay to treatment and crossovers, which would be likely to reduce the reported effect of hip arthroscopy in the trial. Any benefit of hip arthroscopy over conservative care must also be weighed against the complication profile of surgery.

Strengths of this trial include the consent to participate rate among eligible patients (54%) and the follow-up rate (92%). Both of these are high compared with similar trials in orthopaedics, and especially to trials of surgery compared with no surgery, contributing to external and internal validity.[82] The integrated qualitative research optimised recruitment, as it has in other trials.[71] This trial was thoroughly pragmatic, exploring the effectiveness of a strategy of offering hip arthroscopy and conservative care in the everyday reality of an NHS where patients may not always receive or comply with the treatment they are offered, where surgeons and physiotherapists have varying levels of training, skill and expertise, where postoperative care is variable and where there are waiting lists for treatment. The large number of centres ($n = 23$), surgeons ($n = 27$) and physiotherapists ($n = 43$) involved in this trial is a strength, which contributes to the generalisability of our findings. The comparator for this trial was PHT, a fair representation of the best conservative care that can realistically be provided in the UK NHS for these patients. PHT was designed through international consensus and developed, supported and tested in similar ways to other physiotherapist-led conservative care protocols.[83] PHT meets the standards expected of a complex intervention in a RCT and was delivered by musculoskeletal physiotherapists who attended additional training and support events.[3,5,84]

Limitations of this trial include the non-blinding of participants and treating clinicians to allocation. A blinded allocation trial, with a placebo control, would have been better suited to measuring the underlying effect of surgery. In this trial, the pragmatic research question was whether hip arthroscopy or best conservative care was the most effective treatment strategy, leading to an inevitable lack of blinding. Data collection and analysis were performed without revealing treatment allocation. An unexpected difficulty in the performance of the trial was the frequent delay in the delivery of surgery for those patients allocated to hip arthroscopy. It was anticipated that this would be < 3 months in most patients because when the trial was designed there was a strongly enforced NHS target to treat patients within 18 weeks from referral to surgery. However, during the study, this target was a challenge in many hospitals. Therefore, patients allocated to hip arthroscopy often experienced longer times to treatment and, because outcome was measured 12 months after randomisation, were often still within a few months (and in some cases a few weeks) of their operation when the primary outcome was measured. Patients in the hip arthroscopy group had, on average, less time to recover before the primary outcome measurement. A comparison of the outcome of hip arthroscopy participants who had surgery in the first 6 months after randomisation with those who had surgery in the second 6 months showed no significant difference between these groups, suggesting that the systematic difference in time to treatment between groups does not account for the treatment effect. Inferences about the effectiveness of hip arthroscopy compared with PHT are limited to 12-month post-randomisation data. Longer-term follow-up is required to establish if this effect is maintained and if further treatments are required. There will be further follow-up points at 5 and 10 years. The fact that not all surgery or PHT was deemed to be of a high fidelity is also a reflection of the real-world setting in which this trial was conducted. Some surgery was not satisfactory and some participants allocated PHT did not engage with it or complete it. The fidelity assessment showed 'good' treatment in 87% and 70% of hip arthroscopy and PHT groups, respectively. However, these proportions are comparable to other studies and reflect the pragmatism of the trial.[85] Crossover was minimised using techniques developed in the feasibility study. No participants allocated hip arthroscopy received PHT and 14 participants allocated to PHT subsequently changed their mind and decided to have surgery within 12 months. These crossovers cannot account for the results of the trial. Indeed, such crossovers should dilute and so reduce the estimate of the real underlying effect of hip arthroscopy. A further limitation is the timings of the collection of outcome. In both treatment groups, the mean and median data were collected at 6 and 12 months; however, the SD around this was over 30 days in both groups.

Personalised hip therapy is believed to work by improving muscle control, strength around the hip and movement patterns, leading to the avoidance of hip impingement. Surgery is thought to work by reshaping the bone to prevent impingement and by treating painful injuries to articular cartilage and labrum. In this trial, the observed effect of hip arthroscopy over conservative care might be attributable to the surgical procedure, the placebo effect of surgery (given the unblinded nature of this trial), post-surgical rehabilitation or a combination of these factors. The subgroup analysis of those with only cam morphology is suggestive of an increased treatment effect of hip arthroscopy compared with other shapes and this would support the idea that the removal of a cam shape has a specific therapeutic effect. The small number of patients with pincer or mixed cam and pincer morphology in this study leads to less confidence about the influence of reshaping the acetabular rim. Future research should focus on investigating the mechanism of benefit from both arthroscopic surgery and PHT, and on which patients, including impingement types, benefit most from hip arthroscopy or PHT. A priority for further research is an assessment to establish the longer-term clinical effectiveness and cost-effectiveness of the treatments, given the short horizon in the analysis reported.

Chapter 7 Conclusion

Hip arthroscopy in patients with FAI syndrome led to better patient-reported hip-specific outcomes at 12 months after randomisation than best conservative care, supporting the use of this technology in clinical practice. This improvement comes at some cost, and this study did not demonstrate cost-effectiveness of hip arthroscopy compared with conservative care within the first 12 months. Costs continue to be incurred in both groups up to at least 3 years, including operations in more than one-quarter of those allocated to best conservative care. The lifetime cost-effectiveness will be established only when long-term follow-up data are available. Further follow-up at 5 and 10 years, including patient-reported outcome and hip replacement rates, will provide guidance on the best long-term strategy for patients with FAI syndrome. Integrated qualitative research into recruitment was able to maximise study enrolment and may be of benefit in future surgical trials.

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Data-sharing statement

All available data can be obtained from the corresponding author.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Case report forms

Baseline data

Research Associate/Nurse to complete and send copies of the images to the FASHIoN Team

FASHIoN **Site ID:** ☐☐ **Participant ID:** F A S ☐☐☐

Baseline Images

Images required at Baseline: **X-Ray and MRI/MRA/CT** **(All patients)**

A minimum of MRI or MRA or CT is required at baseline. If patients have received more than one type then we would like copies of all these scans.

	Date of Image	
Baseline Image: X-ray	☐☐ ☐☐ ☐☐☐☐	
MRI	☐☐ ☐☐ ☐☐☐☐	Not done ☐
MRA	☐☐ ☐☐ ☐☐☐☐	Not done ☐
CT	☐☐ ☐☐ ☐☐☐☐	Not done ☐

Please return copies of the anonymised baseline on disc in the FREEPOST envelope provided to the FASHIoN team.

Signed:..... Date *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Print Name:.....

Baseline Images V1.0 | 18062014

To be completed by the Research Associate/Nurse

Site ID: ☐☐ **Participant ID:** F A S ☐☐☐

Baseline Data

Patient Characteristics:

1. Which hip is being considered for treatment? (please tick the relevant box)

Left ☐

Right ☐

Both ☐

If 'both' has been indicated please specify the hip the treating surgeon is considering for the study

Left ☐

Right ☐

Please give a brief description of hip symptoms (max 10 words):

2. Duration of hip symptoms (months): ☐☐

3. Is the patient a regular smoker? Yes ☐ No ☐

If **Yes** how many cigarettes per day? ☐☐

How many years has the patient smoked? ☐☐

4. How many *units of alcohol does the patient drink in a normal week? ☐☐

Working out units of alcohol

One unit of alcohol is equivalent to ½ a pint of ordinary beer, lager or cider; one single pub measure of spirits or one small glass of wine.

6. Is the patient diabetic? Yes ☐ No ☐

7. Does the patient have diagnosed chronic renal failure? Yes ☐ No ☐

Signature: .....

Print Name: .....

Date *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Baseline Data Form v1.0 | 18062014

This form is to be filled in by the Research Associate/Nurse once informed consent has been obtained

FASHION

Patient Contact Details

Site ID

Participant ID F A S –

NHS Number

DO NOT SEND THIS PAGE WITH THE PATIENT'S CASE REPORT FORMS (CRFs)

Please return this page in the freepost envelope provided to the FASHIoN office once consent has been given. Please note as many different types of contact as possible.

Title: .....

First Name: ..... **Surname**:

.....

House/Flat Number: ..... **Telephone**

Street name: ..... Home: .....

..... Work: .....

Town/City: ..... Mobile: .....

Postcode: ..... Preferred method/time of contact:

Email: .....@..... .....

Please provide details of two people who would be willing to be contacted by the research team in case the patient changes address.

Title: ..... Title: .....

First Name: ..... First Name: .....

Surname: ..... Surname: .....

House/Flat Number: ..... House/Flat Number: .....

Street name: ..... Street name: .....

....

Town/City: ..... Town/City: .....

Postcode: ..... Postcode: .....

Email: ..... Email: .....

Telephone **Telephone**

Home: ..... Home: .....

Work: ..... Work: .....

Mobile: ..... Mobile: .....

GP DETAILS

Doctor/Surgery Name: .....

Address: .....

.....

Telephone: .....

Research Associate/Nurse signature: .....

Date (dd/mm/yyyy)

Patient Contact Details V 1.0 | 180614

UKFASHION
STUDYING HIP IMPINGEMENT

SITE ID
PATIENT ID FAS-
DATE

Baseline Questionnaire

INSTRUCTIONS

Please read all the instructions before completing the questionnaire

Please follow the instructions for each section carefully.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

We would like to know about your ☐ left ☐ right hip

Date of completion / /

PART 1

This section asks about how active you are.

Q01 Tick one box that best describes your current activity level:

- ☐ I regularly participate in impact sports such as jogging, tennis, skiing or mountaineering
- ☐ I sometimes participate in impact sports
- ☐ I regularly participate in active events, such as golf or bowling
- ☐ I regularly participate in active events such as bicycling
- ☐ I regularly participate in moderate activities such as swimming or unlimited housework/shopping
- ☐ I sometimes participate in moderate activities
- ☐ I regularly participate in mild activities such as walking or limited housework/shopping
- ☐ I sometimes participate in mild activities
- ☐ I am mostly inactive or restricted to minimum activities of daily living
- ☐ I am wholly inactive, dependent on others, and cannot leave residence

Baseline

Version 1.0 | 20/02/2014

PART 2 | INSTRUCTIONS

- These questions ask about the problems you may be experiencing in your hip, how these problems affect your life, and the emotions you may feel because of these problems.
- Please answer each question with respect to the current status, function, circumstances and beliefs related to your hip.
- Consider the last month.
- The questions are formatted so that you can indicate the severity of the problem by marking the line below the question.

PLEASE NOTE

Please mark the line with a slash at the point which most closely represents your situation.

- If you put a mark on the far left, it means that you feel you are significantly impaired. For example:

significantly impaired / _____ no problems at all

- If you put a mark on the far right, it means that you do not think that you have any problems with your hip. For example:

significantly impaired _____ / no problems at all

- If the mark is placed in the middle of the line, this indicates that you are moderately disabled, or in other words, between the extremes of 'significantly impaired' and 'no problems at all'. It is important to put your mark at either end of the line if the extreme descriptions accurately reflect your situation.

If the question asks about something that you do not experience, please tick the option:

☑ I do not do this action in my activities

where this is appropriate.

PART 2 | SECTION 1 | SYMPTOMS AND FUNCTIONAL LIMITATIONS

The following questions ask about symptoms that you may experience in your hip and about the function of your hip with respect to daily activities. Please think about how you have felt most of the time over the past month and answer accordingly.

Q01 How often does your hip/groin ache?

constantly _____ never

Q02 How stiff is your hip as a result of sitting/resting during the day?

extremely stiff _____ not stiff at all

Q03 How difficult is it for you to walk long distances?

extremely difficult _____ not difficult at all

Q04 How much pain do you have in your hip while sitting?

extreme pain _____ no pain at all

Q05 How much trouble do you have standing on your feet for long periods of time?

severe trouble _____ no trouble at all

Q06 How difficult is it for you to get up and down off the floor/ground?

extremely difficult _____ not difficult at all

Q07 How difficult is it for you to walk on uneven surfaces?

extremely difficult _____ not difficult at all

Q08 How difficult is it for you to lie on your affected hip side?

extremely difficult _____ not difficult at all

Q09 How much trouble do you have with stepping over obstacles?

severe trouble _____ no trouble at all

Q10 How much trouble do you have with climbing up/down stairs?

severe trouble _____ no trouble at all

Q11 How much trouble do you have with rising from a sitting position?

severe trouble _____ no trouble at all

Q12 How much discomfort do you have with taking long strides?

extreme discomfort _____ no discomfort at all

Q13 How much difficulty do you have with getting into and/or out of a car?

extreme difficulty _____ no difficulty at all

Q14 How much trouble do you have with grinding, catching or clicking in your hip?

severe trouble _____ no trouble at all

Q15 How much difficulty do you have with putting on/taking off socks, stockings or shoes?

extreme difficulty _____ no difficulty at all

Q16 Overall, how much pain do you have in your hip/groin?

extreme pain _____ no pain at all

PART 2 | SECTION 2 | SPORTS AND RECREATIONAL ACTIVITIES

The following questions ask about your **hip** when you participate in sports and recreational activities. Please think about how you have felt most of the time over the past **month** and answer accordingly.

Q17 How concerned are you about your ability to maintain your desired fitness level?

extremely concerned _____ not concerned at all

Q18 How much pain do you experience in your hip after activity?

extreme pain _____ no pain at all

Q19 How concerned are you that the pain in your hip will increase if you participate in sports or recreational activities?

extremely concerned _____ not concerned at all

Q20 How much has your quality of life deteriorated because you cannot participate in sport/recreational activities?

extremely deteriorated _____ not deteriorated at all

Q21 How concerned are you about cutting/changing directions during your sport or recreational activities?

☐ I do not do this action in my activities

extremely concerned _____ not concerned at all

Q22 How much has your performance level decreased in your sport or recreational activities?

extremely decreased _____ not decreased at all

PART 2 | SECTION 3 | JOB RELATED CONCERNS

The following questions relate to your hip with respect to your current work. Please think about how you have felt most of the time over the past month and answer accordingly.

☐ I do not work because of my hip *(please skip section)*
☐ I do not work for reasons other than my hip *(please skip section)*

Q23 How much trouble do you have pushing, pulling, lifting or carrying heavy objects at work?

☐ I do not do these actions in my activities

severe trouble _____ no trouble at all

Q24 How much trouble do you have with crouching/squatting?

severe trouble _____ no trouble at all

Q25 How concerned are you that your job will make your hip worse?

extremely concerned _____ not concerned at all

Q26 How much difficulty do you have at work because of reduced hip mobility?

extreme difficulty _____ no difficulty at all

PART 2 | SECTION 4 | SOCIAL, EMOTIONAL AND LIFESTYLE CONCERNS

The following questions ask about social, emotional and lifestyle concerns that you may feel with respect to your hip problem. Please think about how you have felt most of the time over the past month and answer accordingly.

Q27 How frustrated are you because of your hip problem?

extremely frustrated _____ not frustrated at all

Q28 How much trouble do you have with sexual activity because of your hip?

☐ This is not relevant to me

severe trouble _____ no trouble at all

Q29 How much of a distraction is your hip problem?

extreme distraction _____ no distraction at all

Q30 How difficult is it for you to release tension and stress because of your hip problem?

extremely difficult _____ not difficult at all

Q31 How discouraged are you because of your hip problem?

extremely discouraged _____ not discouraged at all

Q32 How concerned are you about picking up or carrying children because of your hip?

☐ I do not do this action in my activities

extremely concerned _____ not concerned at all

Q33 How much of the time are you aware of the disability in your hip?

constantly aware _____ not aware at all

PART 3

This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

Q01 In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

The following two questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Q02 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:

☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

Q03 Climbing several flights of stairs:

☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

During the past 4 weeks have you had any of the following problems with your work or other regular activities as a result of your physical health?

Q04 Accomplished less than you would like:

☐ Yes ☐ No

Q05 Were limited in the kind of work or other activities:

☐ Yes ☐ No

During the past 4 weeks, were you limited in the kind of work you do or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

Q06 Accomplished less than you would like:

☐ Yes ☐ No

Q07 Didn't do work or other activities as carefully as usual:

☐ Yes ☐ No

Q08 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not At All
- ☐ A Little Bit
- ☐ Moderately
- ☐ Quite A Bit
- ☐ Extremely

The next three questions are about how you feel and how things have been during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

Q09 Have you felt calm and peaceful?

- ☐ 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

Q10 Did you have a lot of energy?

- ☐ 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

Q11 Have you felt downhearted and blue?

- ☐ 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

Q12 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ 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

PART 4

The following questions ask you about your general health state at the moment. By ticking one box in each group below, please indicate which statement best describes your own health state today.

Q01 Mobility

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

Q02 Self-care

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

Q03 Usual activities (eg work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

Q04 Pain or discomfort

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

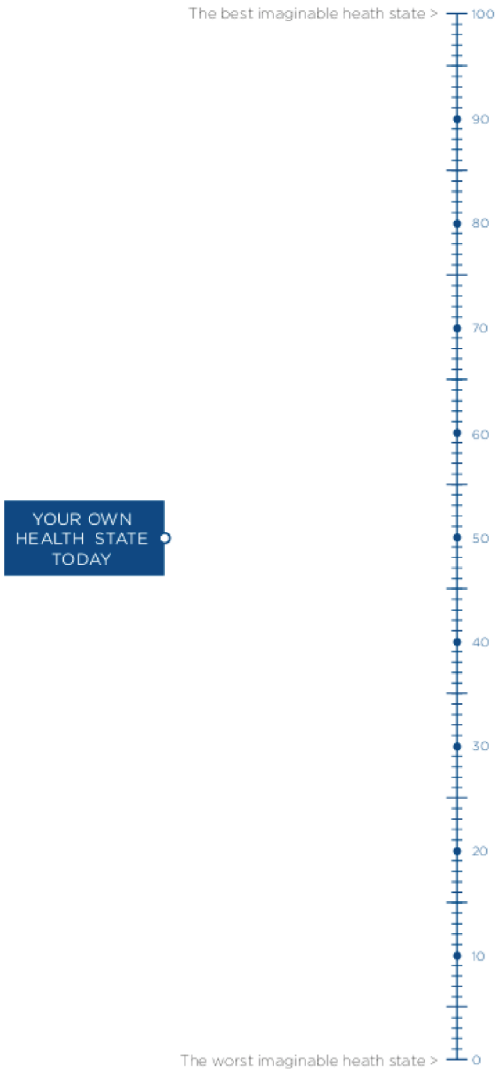
Q05 Anxiety or depression

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

Q06 Health State

To help people say how good or bad a health status is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Please mark an 'X' on the scale below to indicate how your health is **today** and then write the number you marked on the scale in the box at bottom right.



Complications

Q01 In the past 3 months have you been treated for any of the following events?

Wound complication (if you have had surgery)	☐ Yes	☐ No	☐ N/A
Unplanned surgery because of your femoroacetabular impingement	☐ Yes	☐ No	
A regional pain syndrome	☐ Yes	☐ No	
Deep Vein Thrombosis (DVT)	☐ Yes	☐ No	
If yes, did you see the DVT nurse	☐ Yes	☐ No	
If yes, were you prescribed medication?	☐ Yes	☐ No	

Q02 Any other complications? ☐ Yes ☐ No

If yes, please specify:

Q03 Have you had any other unscheduled appointment at hospital because of you femoroacetabular impingement. ☐ Yes ☐ No

If you are unsure about any of these questions please cross here ☐ and someone from the research team will get in contact with you to help you answer these questions.

Complications Version 1.0 | 20/02/2014

UKFASHION
STUDYING HIP IMPINGEMENT

Health Economics: **Baseline**

We would like to find out about your contacts with health and social services over the last 3 months and any extra costs that have been incurred over the same period as a result of your health. Your answers are strictly confidential and anonymous. Your answers are important because they will give persons who make decisions about patient treatment within the National Health Service an idea of the costs involved.

INPATIENT / DAY CARE

Q01 Over the last 3 months have you been admitted to hospital as an inpatient or for day case care? ☐ Yes ☐ No

If yes, please tell us if you can which department of the hospital you went to (speciality) and the number of days you were in hospital. If the speciality is not listed, then please write in the speciality or part of your body as best you can in the box provided.

SPECIALTY	NAME OF HOSPITAL AND WARD	NO OF DAYS IN HOSPITAL
Orthopaedics (your hip/leg)		
Orthopaedics (any other bones)		
Rehabilitation unit		
For any day case care		
For any other surgery Please specify here _____		
Please specify here _____		
Please specify here _____		

VERSION 1.1 | 30.10.2012

OUTPATIENT CARE

Q02 Over the last 3 months have you visited an outpatient clinic in hospital?

☐ Yes ☐ No

If yes, please write the number of visits in the last 3 months in the appropriate box below. If the type of outpatient clinic you attended is not listed then please write this in at the end of the table.

OUTPATIENT CLINIC	NO OF VISITS OVER THE PAST 3 MONTHS
Orthopaedics (about your hip/leg)	
Physiotherapy outpatient clinic (about your hip/leg)	
Physiotherapy outpatient clinic (any other reason)	
Accident & Emergency	
For any other visits Please specify here	
Please specify here	

COMMUNITY CARE

Q03 In the past 3 months, have you seen any health care professionals in the community? ☐ Yes ☐ No

If yes, please indicate the number of contacts over the past 3 months and the average duration of these contacts in minutes. If the type of support you have received is not listed then please write this in at the end of the table.

SERVICE	NO OF CONTACTS OVER PAST 3 MONTHS	AVERAGE DURATION OF CONTACT (MINUTES)
GP visits in surgery		
GP home visits		
GP telephone contacts		
Practice nurse contacts		
District nurse contacts		
Community physiotherapy contacts		
For any other contact Please specify here		
Please specify here		
Please specify here		

Q04 Over the past 3 months, have you been provided with personal social services to make your day to day life easier to manage? ☐ Yes ☐ No

If yes, in the following table please indicate the number of contacts with the service over the last 3 months and the average duration of these contacts in minutes. If the type of support you have received is not listed then please write this in at the end of the table.

SERVICE	NO OF TIMES OVER PAST 3 MONTHS	AVERAGE DURATION OF CONTACT (MINUTES)
Meals on wheels (frozen, daily)		
Meals on wheels (hot, daily)		
Laundry services		
Social worker contacts		
Care worker contacts including help at home		
Community physiotherapy contacts		
For any other service Please specify here		
Please specify here		
Please specify here		

MEDICATIONS

Q05 Have you been prescribed or bought any new medications over the past 3 months? ☐ Yes ☐ No

If yes, please note any medications (including pain relief) that you have been prescribed by a doctor or other health care professional in the past 3 months. Also please include any medication that you have bought yourself without a prescription ("over the counter").

MEDICATION & DOSAGE	NO TIMES DAILY	NO OF DAYS USED	TYPE
EXAMPLE *Ibuprofen topical gel 25ml*	*x2*	*14*	☐ Prescription ☒ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter

AIDS AND ADAPTATIONS

Q06 Have you received or bought any aid or adaptations as a result of your health over the past 3 months? ☐ Yes ☐ No

If yes, in the following table, please indicate the number of aids or items of equipment received. If an item you have received is not listed please write this in and the quantity.

AID OR ADAPTATION	NO RECEIVED	COST (£) (if bought yourself)
Crutches		
Stick		
Walking frame		
Grab rail		
Dressing aids		
Long-handle shoe horns		
Other Please specify here		
Please specify here		
Please specify here		

ADDITIONAL INFORMATION

Q07 Please think of any additional costs over the past 3 months to you, your partner, other family members and friends that have been incurred as a result of your contact with health or social care services or your general health state. If a category of cost is not listed below please add it at the bottom of the table.

NATURE OF COST	COST TO YOU	COST TO PARTNER	COST TO RELATIVES/ FRIENDS
Lost earnings Do not record if annual or compassionate leave was taken or the time off work was made up at a later point			
Childcare			
Help with housework			
Special equipment			
Other Please specify here _____			
Please specify here _____			
Please specify here _____			
Please specify here _____			
Please specify here _____			
Please specify here _____			
Please specify here _____			

Q08 Are you currently working (please tick)?

☐ Yes

If yes, what is your main job?

☐ No If no, is this because of (please tick):

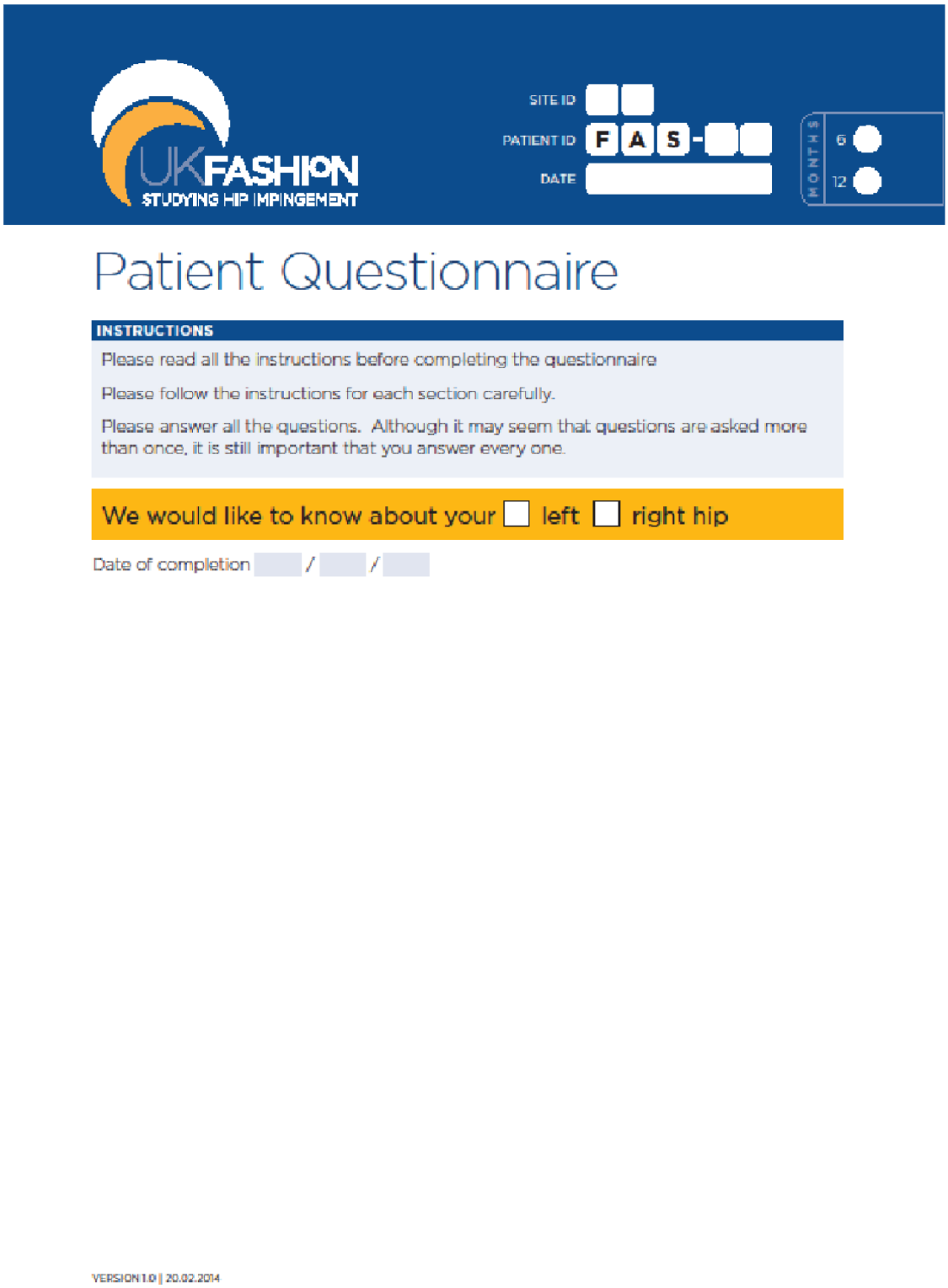
- ☐ Your hip condition
- ☐ Other health reason
- ☐ Unable to work for other reason
- ☐ Retired

Q09 Please indicate if over the last 3 months you have received any of the benefits below. If a benefit you are receiving is not listed below please add it at the bottom of the table.

BENEFIT	BENEFIT RECEIVED OVER THE PAST 3 MONTHS	IF YES, PLEASE ESTIMATE AMOUNT RECEIVED PER WEEK (£)
Attendance Allowance	☐ Yes ☐ No	
Income Support	☐ Yes ☐ No	
Jobseeker's Allowance	☐ Yes ☐ No	
Housing Benefit	☐ Yes ☐ No	
Child tax credit	☐ Yes ☐ No	
Disability Living Allowance – mobility	☐ Yes ☐ No	
Disability Living Allowance – caring	☐ Yes ☐ No	
Pension Credit	☐ Yes ☐ No	
Council Tax Benefit	☐ Yes ☐ No	
Carer's Allowance	☐ Yes ☐ No	
Statutory Sick Pay	☐ Yes ☐ No	
Employment and Support Allowance	☐ Yes ☐ No	
Other Please specify here		
Please specify here		

Follow-up case report forms

Follow-up case report form: 6 and 12 months


UKFASHION
STUDYING HIP IMPINGEMENT

SITE ID
PATIENT ID FAS-
DATE

MONTHS 6 12

Patient Questionnaire

INSTRUCTIONS

Please read all the instructions before completing the questionnaire

Please follow the instructions for each section carefully.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

We would like to know about your ☐ left ☐ right hip

Date of completion / /

VERSION 1.0 | 20.02.2014

PART 1 | INSTRUCTIONS

- These questions ask about the problems you may be experiencing in your hip, how these problems affect your life, and the emotions you may feel because of these problems.
- Please answer each question with respect to the current status, function, circumstances and beliefs related to your hip.
- Consider the last month.
- The questions are formatted so that you can indicate the severity of the problem by marking the line below the question.

PLEASE NOTE

Please mark the line with a slash at the point which most closely represents your situation.

- If you put a mark on the far left, it means that you feel you are significantly impaired. For example:

significantly impaired / _____ no problems at all

- If you put a mark on the far right, it means that you do not think that you have any problems with your hip. For example:

significantly impaired _____ / no problems at all

- If the mark is placed in the middle of the line, this indicates that you are moderately disabled, or in other words, between the extremes of 'significantly impaired' and 'no problems at all'. It is important to put your mark at either end of the line if the extreme descriptions accurately reflect your situation.

If the question asks about something that you do not experience, please tick the option:

☑ I do not do this action in my activities

where this is appropriate.

PART 1 | SECTION 1 | SYMPTOMS AND FUNCTIONAL LIMITATIONS

The following questions ask about symptoms that you may experience in your hip and about the function of your hip with respect to daily activities. Please think about how you have felt most of the time over the past month and answer accordingly.

Q01 How often does your hip/groin ache?

constantly _____ never

Q02 How stiff is your hip as a result of sitting/resting during the day?

extremely stiff _____ not stiff at all

Q03 How difficult is it for you to walk long distances?

extremely difficult _____ not difficult at all

Q04 How much pain do you have in your hip while sitting?

extreme pain _____ no pain at all

Q05 How much trouble do you have standing on your feet for long periods of time?

severe trouble _____ no trouble at all

Q06 How difficult is it for you to get up and down off the floor/ground?

extremely difficult _____ not difficult at all

Q07 How difficult is it for you to walk on uneven surfaces?

extremely difficult _____ not difficult at all

Q08 How difficult is it for you to lie on your affected hip side?

extremely difficult _____ not difficult at all

Q09 How much trouble do you have with stepping over obstacles?

severe trouble _____ no trouble at all

Q10 How much trouble do you have with climbing up/down stairs?

severe trouble _____ no trouble at all

Q11 How much trouble do you have with rising from a sitting position?

severe trouble _____ no trouble at all

Q12 How much discomfort do you have with taking long strides?

extreme discomfort _____ no discomfort at all

Q13 How much difficulty do you have with getting into and/or out of a car?

extreme difficulty _____ no difficulty at all

Q14 How much trouble do you have with grinding, catching or clicking in your hip?

severe trouble _____ no trouble at all

Q15 How much difficulty do you have with putting on/taking off socks, stockings or shoes?

extreme difficulty _____ no difficulty at all

Q16 Overall, how much pain do you have in your hip/groin?

extreme pain _____ no pain at all

PART 1 | SECTION 2 | SPORTS AND RECREATIONAL ACTIVITIES

The following questions ask about your **hip** when you participate in sports and recreational activities. Please think about how you have felt most of the time over the past **month** and answer accordingly.

Q17 How concerned are you about your ability to maintain your desired fitness level?

extremely concerned _____ not concerned at all

Q18 How much pain do you experience in your hip after activity?

extreme pain _____ no pain at all

Q19 How concerned are you that the pain in your hip will increase if you participate in sports or recreational activities?

extremely concerned _____ not concerned at all

Q20 How much has your quality of life deteriorated because you cannot participate in sport/recreational activities?

extremely deteriorated _____ not deteriorated at all

Q21 How concerned are you about cutting/changing directions during your sport or recreational activities?

☐ I do not do this action in my activities

extremely concerned _____ not concerned at all

Q22 How much has your performance level decreased in your sport or recreational activities?

extremely decreased _____ not decreased at all

PART 1 | SECTION 3 | JOB RELATED CONCERNS

The following questions relate to your hip with respect to your current work. Please think about how you have felt most of the time over the past month and answer accordingly.

☐ I do not work because of my hip *(please skip section)*
☐ I do not work for reasons other than my hip *(please skip section)*

Q23 How much trouble do you have pushing, pulling, lifting or carrying heavy objects at work?

☐ I do not do these actions in my activities

severe trouble _____ no trouble at all

Q24 How much trouble do you have with crouching/squatting?

severe trouble _____ no trouble at all

Q25 How concerned are you that your job will make your hip worse?

extremely concerned _____ not concerned at all

Q26 How much difficulty do you have at work because of reduced hip mobility?

extreme difficulty _____ no difficulty at all

PART 1 | SECTION 4 | SOCIAL, EMOTIONAL AND LIFESTYLE CONCERNS

The following questions ask about social, emotional and lifestyle concerns that you may feel with respect to your hip problem. Please think about how you have felt most of the time over the past month and answer accordingly.

Q27 How frustrated are you because of your hip problem?

extremely frustrated _____ not frustrated at all

Q28 How much trouble do you have with sexual activity because of your hip?

☐ This is not relevant to me

severe trouble _____ no trouble at all

Q29 How much of a distraction is your hip problem?

extreme distraction _____ no distraction at all

Q30 How difficult is it for you to release tension and stress because of your hip problem?

extremely difficult _____ not difficult at all

Q31 How discouraged are you because of your hip problem?

extremely discouraged _____ not discouraged at all

Q32 How concerned are you about picking up or carrying children because of your hip?

☐ I do not do this action in my activities

extremely concerned _____ not concerned at all

Q33 How much of the time are you aware of the disability in your hip?

constantly aware _____ not aware at all

PART 2

This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

Q01 In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

The following two questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Q02 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:

☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

Q03 Climbing several flights of stairs:

☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

During the past 4 weeks have you had any of the following problems with your work or other regular activities as a result of your physical health?

Q04 Accomplished less than you would like:

☐ Yes ☐ No

Q05 Were limited in the kind of work or other activities:

☐ Yes ☐ No

During the past 4 weeks, were you limited in the kind of work you do or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

Q06 Accomplished less than you would like:

☐ Yes ☐ No

Q07 Didn't do work or other activities as carefully as usual:

☐ Yes ☐ No

Q08 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not At All
- ☐ A Little Bit
- ☐ Moderately
- ☐ Quite A Bit
- ☐ Extremely

The next three questions are about how you feel and how things have been during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

Q09 Have you felt calm and peaceful?

- ☐ 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

Q10 Did you have a lot of energy?

- ☐ 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

Q11 Have you felt downhearted and blue?

- ☐ 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

Q12 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ 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

PART 3

The following questions ask you about your general health state at the moment. By ticking one box in each group below, please indicate which statement best describes your own health state today.

Q01 Mobility

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

Q02 Self-care

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

Q03 Usual activities (eg work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

Q04 Pain or discomfort

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

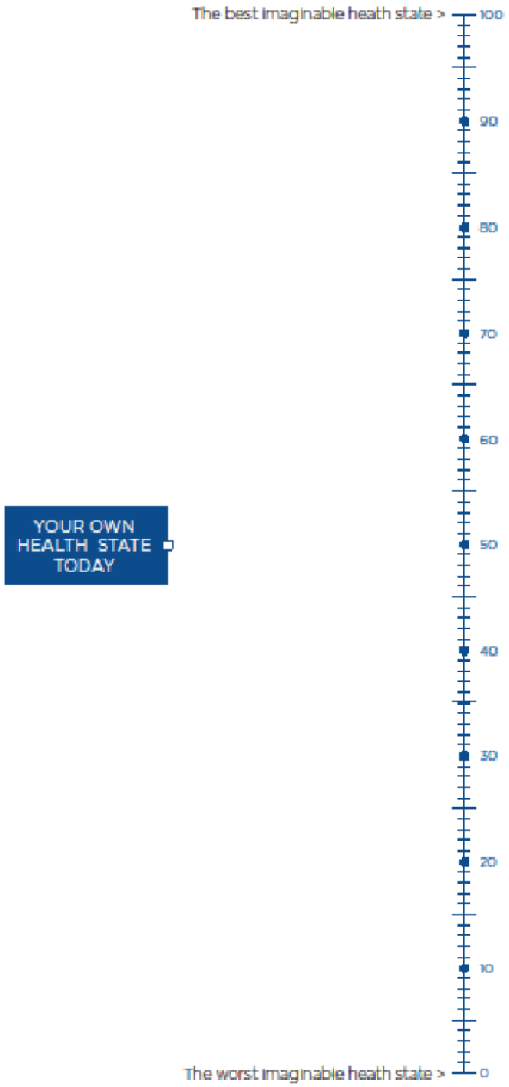
Q05 Anxiety or depression

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

Q06 Health State

To help people say how good or bad a health status is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

Please mark an 'X' on the scale below to indicate how your health is **today** and then write the number you marked on the scale in the box at bottom right.



PART 6

Q01 In the past 3 months have you been treated for any of the following events?

Wound complication (if you have had surgery)	☐ Yes	☐ No	☐ N/A
Unplanned surgery because of your femoroacetabular impingement	☐ Yes	☐ No	
A regional pain syndrome	☐ Yes	☐ No	
Deep Vein Thrombosis (DVT)	☐ Yes	☐ No	
If yes, did you see the DVT nurse	☐ Yes	☐ No	
If yes, were you prescribed medication?	☐ Yes	☐ No	

Q02 Any other complications? ☐ Yes ☐ No

If yes, please specify:

Q03 Have you had any other unscheduled appointment at hospital because of you femoroacetabular impingement. ☐ Yes ☐ No

If you are unsure about any of these questions please cross here ☐ and someone from the research team will get in contact with you to help you answer these questions.

That is the end of the questionnaire.

Please check that you have completed all sections.

Please keep a record of any days off work and hospital or medical procedures you under go as a result of your hip impingement.

In three months we will send you another questionnaire which will ask you for these details. Please use the reply-paid envelope to return that questionnaire to us.

Thank you very much for your time.

Health Economics: **6 Month Follow-up**

We would like to find out about your contacts with health and social services over the last 6 months and any extra costs that have been incurred over the same period as a result of your health. Your answers are strictly confidential and anonymous. Your answers are important because they will give persons who make decisions about patient treatment within the National Health Service an idea of the costs involved.

INPATIENT / DAY CARE

Q01 Over the last 6 months have you been admitted to hospital as an inpatient or for day case care? ☐ Yes ☐ No

If yes, please tell us if you can which department of the hospital you went to (speciality) and the number of days you were in hospital. If the speciality is not listed, then please write in the speciality or part of your body as best you can in the box provided.

SPECIALTY	NAME OF HOSPITAL AND WARD	NO OF DAYS IN HOSPITAL
Orthopaedics (your hip/leg)		
Orthopaedics (any other bones)		
Rehabilitation unit		
For any day case care		
For any other surgery Please specify here		
Please specify here		
Please specify here		

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OUTPATIENT CARE

Q02 Over the last 6 months have you visited an outpatient clinic in hospital?

☐ Yes ☐ No

If yes, please write the number of visits in the last 6 months in the appropriate box below. If the type of outpatient clinic you attended is not listed then please write this in at the end of the table.

OUTPATIENT CLINIC	NO OF VISITS OVER THE PAST 6 MONTHS
Orthopaedics (about your hip/leg)	
Physiotherapy outpatient clinic (about your hip/leg)	
Physiotherapy outpatient clinic (any other reason)	
Accident & Emergency	
For any other visits Please specify here	
Please specify here	

COMMUNITY CARE

Q03 In the past 6 months, have you seen any health care professionals in the community? ☐ Yes ☐ No

If yes, please indicate the number of contacts over the past 6 months and the average duration of these contacts in minutes. If the type of support you have received is not listed then please write this in at the end of the table.

SERVICE	NO OF CONTACTS OVER PAST 6 MONTHS	AVERAGE DURATION OF CONTACT (MINUTES)
GP visits in surgery		
GP home visits		
GP telephone contacts		
Practice nurse contacts		
District nurse contacts		
Community physiotherapy contacts		
For any other contact Please specify here		
Please specify here		
Please specify here		

Q04 Over the past 6 months, have you been provided with personal social services to make your day to day life easier to manage? ☐ Yes ☐ No

If yes, in the following table please indicate the number of contacts with the service over the last 6 months and the average duration of these contacts in minutes. If the type of support you have received is not listed then please write this in at the end of the table.

SERVICE	NO OF TIMES OVER PAST 6 MONTHS	AVERAGE DURATION OF CONTACT (MINUTES)
Meals on wheels (frozen, daily)		
Meals on wheels (hot, daily)		
Laundry services		
Social worker contacts		
Care worker contacts including help at home		
Community physiotherapy contacts		
For any other service Please specify here		
Please specify here		
Please specify here		

MEDICATIONS

Q05 Have you been prescribed or bought any new medications over the past 6 months? ☐ Yes ☐ No

If yes, please note any medications (including pain relief) that you have been prescribed by a doctor or other health care professional in the past 6 months. Also please include any medication that you have bought yourself without a prescription ("over the counter").

MEDICATION & DOSAGE	NO TIMES DAILY	NO OF DAYS USED	TYPE
EXAMPLE *Ibuprofen topical gel 25ml*	*x2*	*14*	☐ Prescription ☒ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter
			☐ Prescription ☐ Over the counter

AIDS AND ADAPTATIONS

Q06 Have you received or bought any aid or adaptations as a result of your health over the past 6 months? ☐ Yes ☐ No

If yes, in the following table, please indicate the number of aids or items of equipment received. If an item you have received is not listed please write this in and the quantity.

AID OR ADAPTATION	NO RECEIVED	COST (£) (if bought yourself)
Crutches		
Stick		
Walking frame		
Grab rail		
Dressing aids		
Long-handle shoe horns		
Other Please specify here		
Please specify here		
Please specify here		

ADDITIONAL INFORMATION

Q07 Please think of any additional costs over the past 6 months to you, your partner, other family members and friends that have been incurred as a result of your contact with health or social care services or your general health state. If a category of cost is not listed below please add it at the bottom of the table.

NATURE OF COST	COST TO YOU	COST TO PARTNER	COST TO RELATIVES/ FRIENDS
Lost earnings Do not record if annual or compassionate leave was taken or the time off work was made up at a later point			
Childcare			
Help with housework			
Special equipment			
Other Please specify here			
Please specify here			
Please specify here			
Please specify here			
Please specify here			
Please specify here			
Please specify here			

Q08 Are you currently working (please tick)?

☐ Yes If yes, what is your main job? (please specify below)

.....

☐ No If no, is this because of (please tick):

- ☐ Your hip condition
- ☐ Other health reason
- ☐ Unable to work for other reason
- ☐ Retired

Q09 Please indicate if, over the last 6 months, you have received any of the benefits below. If a benefit you are receiving is not listed below please add it at the bottom of the table.

BENEFIT	BENEFIT RECEIVED OVER THE PAST 6 MONTHS	IF YES, PLEASE ESTIMATE AMOUNT RECEIVED PER WEEK (£)
Attendance Allowance	☐ Yes ☐ No	
Income Support	☐ Yes ☐ No	
Jobseeker's Allowance	☐ Yes ☐ No	
Housing Benefit	☐ Yes ☐ No	
Child tax credit	☐ Yes ☐ No	
Disability Living Allowance – mobility	☐ Yes ☐ No	
Disability Living Allowance – caring	☐ Yes ☐ No	
Pension Credit	☐ Yes ☐ No	
Council Tax Benefit	☐ Yes ☐ No	
Carer's Allowance	☐ Yes ☐ No	
Statutory Sick Pay	☐ Yes ☐ No	
Employment and Support Allowance	☐ Yes ☐ No	
Other Please specify here		
Please specify here		

Follow-up case report form: 2 and 3 years – further procedures

Site ID ☐☐

Patient ID ☐☐☐-☐☐☐

Date ☐☐/☐☐/☐☐☐☐

Further Procedures Questionnaire

We would like to know about your Left ☐ Right ☐ hip

1.) In the last year have you had treatment from a surgeon for problems with your hip? Yes ☐ No ☐

If **yes**, have you undergone any of the following procedures?

Hip arthroscopy Yes ☐ No ☐

Total hip replacement Yes ☐ No ☐

Other Yes ☐ No ☐

If other, please specify:- ……

……

If **yes**, then please specify the following:

Date of operation/procedure ……

Name of hospital ……

Name of treating surgeon ……

2.) In the last year have you had treatment from a Physiotherapist for problems with your hip? Yes ☐ No ☐

If **yes**, please specify the treatment given

Exercises Yes ☐ No ☐

Other Yes ☐ No ☐

If other, please specify:- ……

……

3.) In the last year have you had treatment from a specialist other than a surgeon or physiotherapist for your hip? Yes ☐ No ☐

If other, please specify the type of speciality and treatment received:- ……

……

……

Thank you for completing the questionnaire
Please return the questionnaire in the reply-paid envelope.

Surgical case report forms

This form is to be filled in by the treating surgeon

FASHION

Site ID: ☐☐ Participant ID: F A S ☐☐☐

Hip Arthroscopy Case Report Form

Patient Initials: ☐☐☐

Date of Birth *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Date of Surgery *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Key stage undertaken		Please tick to confirm completed	If not completed please give a reason
1.	General anaesthetic with muscle relaxation	☐	
2.	Supine or lateral patient positioning	☐	
3.	Operating table used with facility for traction and range of movement testing	☐	
4.	Arthroscopy of central compartment	☐	
5.	Arthroscopy of peripheral compartment	☐	
6.	Entire acetabular labrum examined	☐	
7.	Entire articular surface examined	☐	
8.	Confirmed impingement has been relieved using either range of movement testing or an image intensifier.	☐	
9.	Did the patient have any intraoperative complications e.g. fracture, iatrogenic cartilage damage, anaesthetic problems?	☐	Please specify the complication(s) and solution:-

10. Did you prescribe your standard post-operative rehabilitation/physiotherapy for this patient?

Yes ☐ No ☐

If No, please provide a brief description of your post-operative rehabilitation prescription below.

11.	Attach an anonymised copy of the operative note to this CRF. NB: Note the Participant ID on the copy	☐	
12.	Attach at least two intraoperative photo's to show the initial pathology and subsequent surgical solution.	☐	

Signed:_____ Date *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Print Name:_____

Hip Arthroscopy CRF V1.0| 18/06/2014

Research Associate/Nurse to complete and send to the FASHIoN Team

Site ID: ☐☐ Participant ID: F A S ☐☐☐

Post-op MRI

Complete for all patients who have undergone Arthroscopic Surgery.

Date of Post-op MRI Image: ☐☐ ☐☐ ☐☐☐☐

Date Post-op MRI image uploaded to Clinical Graphics BV: ☐☐ ☐☐ ☐☐☐☐

Name of Person uploading image: .....

Signed: ..... Date *(dd/mm/yyyy)*: ☐☐ ☐☐ ☐☐☐☐

Print Name: .....

Post-op MRI V1.0 | 18062014

To be completed by the Research Associate/Nurse

FASHION

Site ID: ☐☐ **Participant ID:** F A S ☐☐☐

Surgery - 6 Week Complications

In the past 6 weeks has the patient experienced or been treated for any of the following events?

1. **Numbness in the groin leg or foot?** Yes ☐ No ☐

   If yes, please give details: .....

   .....

2. **Wound infection?** Yes ☐ No ☐

   Was the wound i) Deep ☐ ii) Superficial ☐

   Was a course of antibiotics prescribed? Yes ☐ No ☐

   Was further surgery required? Yes ☐ No ☐

3. **Hip fracture (break)** Yes ☐ No ☐

   If yes, please give details: .....

   .....

4. **Further surgery because of your hip impingement?** Yes ☐ No ☐

   If yes, please give details: .....

   .....

5. **Problems with pain medications for your hip impingement?** Yes No

   If yes, please give details: .....

   .....

6. **Problems with hip joint injections** Yes ☐ No ☐

   If yes, please give details: .....

   .....

7. **Muscle soreness from exercises that you have been undertaking?** Yes ☐ No ☐

   If yes, please give details: .....

   .....

8. **A regional pain syndrome?** Yes ☐ No ☐

   If yes, please give details: .....

   .....

To be completed by the Research Associate/Nurse

9.	Deep Vein Thrombosis (DVT)?	Yes ☐	No ☐
	If yes, did you see the DVT nurse?	Yes ☐	No ☐
	If yes, were you prescribed medication?	Yes ☐	No ☐
10.	Any other complications?	Yes ☐	No ☐

If yes, please give details: .....

.....

11.	Have you had any other unscheduled appointment at hospital because of your hip impingement?	Yes ☐	No ☐

If yes, please give details: .....

.....

Research Associate/Research Nurse Name: .....

Research Associate/Research Nurse Signature : .....

Date: ☐☐ ☐☐ ☐☐☐☐
D D M M Y Y Y Y

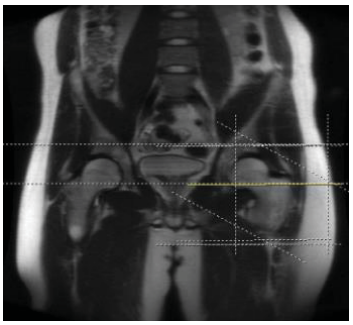
Postoperative magnetic resonance imaging Instructions

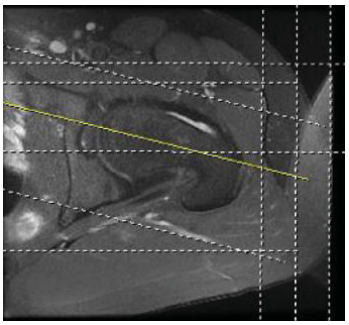
Imaging Instructions

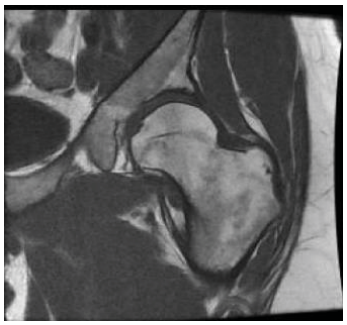
Area to be Imaged	Index hip (the hip that has had arthroscopic FAI surgery as part of the UK FASHIoN study)
Timing	MRI Scan should be done at least 6 weeks post operatively
Patient Position	Supine, both hips internally rotated
Sequences	Proton dense fat suppression sequence acquired in axial plane Slice thickness = between 4-5 mm Gap thickness = 10% No phase wrap
	T1 sequence acquired in coronal oblique (along the line of the femoral neck) plane Slice thickness = between 4-5 mm Gap thickness = 10% No phase wrap
	Proton dense fat suppression 3-D volume acquisition acquired in axial plane Slice thickness = maximum 1.5-2 mm No gap No phase wrap
Field of view	Height = just above the top of acetabulum to just below the lesser trochanter Width = 20cm centred on the centre of femoral head
Matrix	256 x 256 pixels

Examples of MRI

Localiser with top and bottom of axial range marked. Centred medially to the femoral head. Range is the same for axial and volume scan.	Axial image with the alignment of the coronal marked	Coronal Oblique Image







Imaging Instructions v 2.0 | 18062014

Method for Establishing Adequacy of Surgery Performed in FASHIoN Trial

Aim

to provide a semi-objective method to determine the quality of surgical bone reshaping in FASHIoN study participants. By;

- Confirming what surgery, the surgeon, intended to perform.
- Determining whether the surgical plan was executed to an adequate standard.

Data Collection:

Operation note:

Establish whether the surgeon undertook cam and or pincer resection.

Intraoperative Images:

Evaluate the pre treatment pathology and adequacy of the correction.

Post op MRI:

The adequacy of reshaping surgery will be judged according to whether the surgeon stipulated if a cam or pincer resection was performed. The following categories will be used to judge the reshaping;

1. Satisfactory reshaping
2. Borderline adequate reshaping
3. Inadequate reshaping
4. No appreciable change to morphology

Only surgery in categories 1 and 2 will be deemed adequate.

Cases where reshaping was not undertaken (e.g. hip found to be arthritic or different pathology identified) will be judged on a case by cases basis taking on board the surgeons notes and other evidence (e.g. intra operative photos).

The lowest score in the following domains will determine the category of surgery.

Cam Resection:

Head sphericity

Head sphericity	Grade
Spherical Head	1
Mostly spherical	2
Large aspehicity	3
No appreciable change	4

Head Neck Transition:

Head neck transition	Grade
Smooth transition	1
Areas of abrupt transition	2
Irregular transition/ sharp spikes	3
No appreciable change	4

Pincer Resection

Rim morphology	Grade
Smooth rim, no focal prominence	1
Small focal prominence	2
Large rim prominence	3
No appreciable change	4

Additional Data Collected (not be used to judge adequacy of surgery)

Cartilage; single worst area; grades 1-4

Cartilage treatment; chondroplasty, microfracture, glue repair, debridement of defect

Labrum; normal, degenerate, ossified, tear (partial detachment, complete detachment, degenerative or radial tear),

Labrum treatment; nil, debridement, shrinkage, resection, anchor repair

Osteophytes; present in cotyloid fossa, rim or head neck junction

Personalised hip therapy case report form

Date of visit and treating physiotherapist's initials (e.g. 27/3/10, JY)	**…./…./….** **Initials:**	**…./…./….** **Initials:**
If patient UTA'd or DNA'd visit (please tick ☐)		
Length and the type of consultation (e.g. 20 mins face to face/via telephone)		
Discharged (please tick ☐)		
Core Modalities used (please tick ☐)		
1. Assessment / Reassessment		
2. Education and advice		
3. Help with pain relief		
4.a. Supervised exercises in clinic		
4.b. Exercise prescription given		
4.c. Exercise diary given / reviewed		
4.d Exercise progressed (please state e.g. ↑ reps, harder exercises)		
Type of exercises provided (please state)		
Ex Number from Core:		
Ex Number from Core:		
Ex Number from Core:		
Ex Number from Core:		
Ex Number from Core:		
Ex Number from Core:		
Other none- core Exercise : (please state)		
Other none- core Exercise : (please state)		

Other treatment used: (please state e.g. manual therapy, hip steroid injection, orthotics)		
Adverse Events: (e.g. muscle soreness, injury whilst exercising)		
General Comments:		

Personalised hip therapy manual

UK Full Randomised Controlled Trial of Arthroscopic Surgery for Hip Impingement versus best CoNventional Care

REC 14/WM/0124 | HTA 13/103/02 | ISRCTN64081839

FASHION
STUDYING HIP IMPINGEMENT

PERSONALISED HIP THERAPY

The Manual

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NHS
National Institute for Health Research

Personalised Hip Therapy Manual version 2 | 28072014

Contents

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2. Background

2.1 Femoroacetabular impingement (FAI)

Until recently, there was little understanding of the causes of hip pain in young adults. A few of these patients had established osteoarthritis, inflammatory arthritis, avascular necrosis, fractures or childhood hip disease, but the majority had no specific diagnosis. In the last few years there has been increasing recognition of the syndrome of FAI, which seems to account for a large proportion of the previously undiagnosed cases of hip pain in young adults.[1,2] Subtle deformities in the shape of the hip (ball and socket joint) combine to cause impingement between femoral head (ball) or neck and the anterior rim of the acetabulum (socket), most often in flexion and internal rotation.[1,3] Excess contact forces lead to damage to the acetabular labrum (fibrocartilage rim of the socket) and the adjacent acetabular cartilage surface.[1] FAI seems to be associated with progressive articular degeneration of the acetabulum and may account for a significant proportion of so called idiopathic osteoarthritis, although this remains unproven.[3] The shape abnormalities of the hip joint are typically divided into three categories:[3]

- Cam-type, in which the femoral head is oval rather than round, or there is prominent bone on the femoral neck;
- Pincer-type, in which the rim of the acetabulum is too prominent, in one or more areas of its circumference;
- Mixed-type hip impingement, which is a combination of cam and pincer types.

Surgery can be performed to improve bone shapes in order to prevent impingement between the femoral neck and rim of the acetabulum. In the case of cam-type FAI this usually involves removal of bone at the femoral head-neck junction. In the case of pincer-type FAI, it may involve removal of bone at the rim of the acetabulum. At the same time as bony shape improvement, any soft tissue damage to the cartilage or labrum as a result of the FAI is debrided, repaired or reconstructed. Surgery can be undertaken using either keyhole (arthroscopic surgery) or more traditional open surgery to access the hip joint and correct the hip shape abnormalities associated with FAI.

Surgery for FAI has evolved more quickly than our understanding of the epidemiology or natural history of the condition[4-8], yet it is becoming an established treatment within the NHS. The risks of complications from open surgery are greater than those for arthroscopic surgery[9] and current evidence suggests that the outcomes of arthroscopic treatment for the symptoms of FAI are comparable to open surgery.[10] Consequently, hip arthroscopy for FAI is a rapidly growing new cost pressure for the NHS. Three systematic reviews have shown that no RCTs have been conducted to measure the clinical or cost effectiveness of either surgery or non-operative care for FAI[8,11-13], and we have recently confirmed this in a Cochrane systematic review (not yet published). In particular there is no RCT of hip arthroscopy compared with conventional care in patients with FAI.

Multi-centre randomised controlled trials (RCTs) are acknowledged to be the best design for evaluating the effectiveness of health care interventions as they provide robust evidence.[14,15] However, there are often major challenges in performing RCTs of surgical technologies[25], and there have been concerns that an RCT of hip arthroscopy in FAI might not be feasible.

2.2. Feasibility and pilot studies

A feasibility and pilot study commissioned by HTA (HTA 10/41) has been completed. It comprised: (i) a pre-pilot phase including patient and clinician surveys and interviews, and a systematic review of non-operative care; (ii) a workload survey of hip arthroscopy for FAI; (iii) development of best conventional care and arthroscopic surgery protocols; (iv) a pilot RCT to measure recruitment rate; and (v) an integrated programme of qualitative research (IQR) to understand and optimise recruitment.

2.3 Scientific plausibility of Personalised Hip Therapy (PHT)

The symptoms of FAI are believed to be the result of impingement between the femoral head and the acetabulum (the hip ball and socket joint) due to abnormalities of shape and pelvic orientation. These abnormalities are thought to predispose to early and repetitive contact between the femoral head and the acetabular labral and articular surfaces during movement of the hip joint. This contact may cause damage to the soft tissues around the hip including the labrum, which then causes pain.

The personalised hip programme (PHT) has two goals:

- Control and reduce symptoms
- Prevent recurrence of symptoms

The programme will achieve this by teaching patients new techniques and ways of moving during everyday tasks and leisure activities to reduce and avoid hip impingement. PHT will focus on improving the stability and fine control of movement around the hip, as well as improving the strength and flexibility of the joints and muscles close to the hip. Through this PHT patients will be equipped with the right knowledge and skills to modify and maintain ways of moving to reduce and avoid impingement. These improved movement patterns are consciously learnt to begin with but become routine with practice over time.

The programme will provide patients with a high level of understanding of their FAI. Following a detailed assessment the physiotherapist will prescribe a personalised rehabilitation programme that is individualised to each patient's clinical presentation, activity levels and expectations. Over a series of between 6 to 10 treatment contacts, the programme will be progressed guided by the individual requirements and progress of each patient.

Any damaged soft tissues including the labrum that are so acutely painful that engagement in exercise is impossible will be subjected to a period of relative rest with the PHT. Soft tissues including the labrum have the ability to heal naturally, which can take up to several weeks or months. After this period provided that the aggravating impingement has been reduced by improved hip and local joint control methods further painful impingement will be reduced. This is thought to prevent further progress of the FAI.

Several studies have shown the lack of clear association between imaging findings and clinical symptoms of pain and functional limitations. For example studies have found MRI abnormalities in people without any pain and some people with severe knee pain do not have observable x-ray abnormalities. Not much is yet known about the influence of the soft tissues (particularly muscles) in the symptoms of FAI[16], but some evidence concluded that there is a significant soft tissue component in FAI and that it may involve other joints including the lumbo-

sacral joint.[17] Postural abnormalities and muscular imbalances are clear targets for treatment in order to prevent recurrence of FAI symptoms. For example shortening of hip flexors and erector spinae is accompanied by weakness in gluteal and abdominal muscles. These lead to increased anterior tilt in the pelvis and this may contribute to abnormal positioning of the acetabulum and abnormal load transmission across the hip. Other presentations may include long and weak iliopsoas muscle, causing excessive anterior glide and pressure of the femoral head on anterior joint structures during flexion, including the capsule. Treatment approaches that incorporate muscle balance exercise can target these muscles and improve movement patterns.[18]

2.4 Effectiveness of other physiotherapy regimes

Research has shown that exercise is an effective treatment for many types of musculoskeletal pain[19,20], and has identified that exercise-based programmes can produce similar improvements in symptoms to surgery.[21] Personalised regimes of physiotherapy care have been effective and sometimes superior to surgery in managing musculoskeletal problems, with the advantage of significantly less risk than that associated with surgery.

Some examples include:

1. Knee arthroscopy used to be a routine treatment for patients with knee osteoarthritis. We now recognise after performing similar large scale randomised controlled trials that regimes of pain medication and physiotherapy-led exercise are more effective at managing a patients symptoms without the risks of surgery.[22,23]
2. Similar findings have been shown for the treatment of knee meniscal tears where exercise based physiotherapy is equally effective as surgery without the same level of risk.[24]
3. A large randomised trial of lumbar spine fusion versus intensive rehabilitation supervised by physiotherapist found no difference in outcome between groups but significantly less risk in the non-surgical treatment group.[25]

2.5 Define a protocol for best conventional care (comparator)

We performed a systematic review of non-operative care for FAI. This revealed little evidence of a standard for best conventional care, even though many NHS commissioners describe 'failure of conventional care' as a prerequisite for surgery.[26] There was some evidence that physiotherapy-led non-operative care is most frequently used.[11] This is complemented by established theory and evidence supporting treatment effects for physiotherapy in other painful musculoskeletal conditions including osteoarthritis and back pain.[27,28]

We used a combination of consensus methods (Delphi and Nominal Group techniques) among physiotherapists to agree a protocol for 'best conventional care'. We advertised to relevant networks of the Chartered Society of Physiotherapy (CSP) through their interactive communication system (iCSP) and in the *Frontline* magazine (twice monthly magazine posted to 52,000 CSP members in the UK). These advertisements invited physiotherapists to help develop a consensus for a best conventional care treatment protocol for FAI. Electronic invitations were also sent to physiotherapists in the United States and Australia known to us through previous collaborative work on FAI. To encourage a process of 'snowball sampling' within the international community, these therapists were encouraged to invite colleagues with experience and interest in managing FAI to join in the consensus process.

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We developed a physiotherapy-led, four component protocol, to be delivered over at least 12 weeks with a minimum of 6 one-to-one treatment contacts. It includes: (i) a detailed patient assessment; (ii) education and advice about FAI; (iii) help with pain relief including hip joint steroid injections; and (iv)an exercise programme that has the key features of individualisation, supervision and progression. We used a patient focus group to choose the most acceptable name for this protocol of best conventional care. The group made it clear that we should express that this was a coherent and valid alternative to surgery and different to physiotherapy likely to have been received already, and recommended the name Personalised Hip Therapy (PHT).

In the development of PHT we struck a balance between the need for a meaningful comparator for hip arthroscopy, the need to ensure PHT is different to previous physiotherapy that FAI patients may have experienced and the need for PHT to be deliverable in the NHS outside a trial. UK physiotherapists and patients felt that PHT was 'best' in that not all patients currently receive such a comprehensive package, but 'conventional' in that all its elements are widely used and the package is deliverable within usual constraints in the NHS.

3. Personalised Hip Therapy (PHT)

The personalised hip therapy programme is designed with 4 core components. Each patient should receive all four 4 core components over at least a 12 week programme. Optional additional components can be used where appropriate and additional symptoms that patients with femoroacetabular impingement (FAI) may present with can also be treated as per the treating physiotherapists preferred methods. All details of the programme and any additional interventions used must be recorded on the Case Report Form.

3.1 Patient education and advice

1. Education about FAI and available treatments
2. Advice about posture, gait and lifestyle behaviour modifications to try to avoid FAI. These may include:
    - Measures to encourage posterior pelvic tilt (reduce pelvic inclination)
    - Positioning when sitting, standing, sit to stand
    - Positioning when sleeping
    - Positioning when running / cycling where relevant
3. Advice about activities of daily living to try to avoid FAI (reducing / avoiding deep flexion, adduction and internal rotation of hip)
4. Advice about relative rest (for acute pain where patients cannot engage with their exercise-based personal hip programme) given that soft tissues take at least 8-10 weeks to heal. In particular, relative rest in a specific ROM where pain in that particular ROM is likely to represent ongoing impingement. Specific activity/sport technique advice and modification. Examples include running with a broader base to encourage abduction, cycling with less internal rotation on pedals, skiing with skis further apart and using knee flexion more than hip flexion to lower centre of gravity.

3.2 Patient assessment

1. History: to include:

- History of presenting complaint
- Relieving and aggravating factors
- Past Medical History
- Medications
- Previous treatments tried
- Social History including occupation
- Patients concerns, fears and beliefs
- Patients individual requirements and expectations.

2. Examination

- Determine pain-free, passive ROM in the hip
- Determine the strength of motion in the hip in flexion, extension, abduction, adduction, internal and external rotation.
- Impingement test

3.3 Help with pain relief

1. Advice about anti-inflammatory medication for 2 to 4 weeks.
2. Advice about simple analgesics if they do not respond well to anti-inflammatory medication.
3. Engagement in, and adherence to, a personalised exercise programme

3.4 Exercise-based hip programme

1. An exercise programme that has the key features of individualisation, progression and supervision.
2. A phased exercise programme that begins with muscle control work, and progresses to stretching and strengthening with increasing ROM and resistance.
3. Muscle control / stability exercise (targeting pelvic and hip stabilisation, gluteal and abdominal muscles)
4. Strengthening / resistance exercise firstly in available range (pain-free ROM), and targets:
    - Gluteus maximus - extension
    - Short external rotators – external rotation
    - Gluteus medius – abduction
    - Abdominal muscles
    - Lower limb in general
5. Stretching exercise to improve hip external rotation and abduction in extension and flexion (but not vigorous stretching – no painful hard end stretches). Other muscles to be targeted if relevant for the patient include iliopsoas, hip flexors and rotators.
6. Exercise progression in terms of intensity and difficulty, gradually progressing to activity or sport-specific exercise where relevant.
7. A personalised and written exercise prescription that is progressed and revised over treatment sessions.
8. Encourage motivation and adherence through the use of a patient exercise diary to review progress.
9. Patients to have access to therabands, exercise balls and exercise mats.

4. Delivery of care

1. Care provided over at least 12 weeks
2. A minimum of 6 'contacts' with the physiotherapist over 12 weeks
3. Ideally all 6 contacts are face-to-face but at least 3 should be face-to face, others can be via telephone/email support where that is needed due to geographical distance.
4. Further 'booster' follow-ups can be arranged between 12 weeks and 6 months
5. The maximum total number of contacts with physiotherapist is 10 including the optional further booster sessions.
6. Care provided by the same physiotherapist throughout where possible
7. Assessment between treatment sessions will be done by:
   - Subjective assessment
     Questions such as how do you currently rate your pain? Are your symptoms improving?
   - Objective assessment
     Pain levels using VAS
     Pain free ROM
     Exercise ability
   - Exercise adherence
     Review exercise diary and questions such as have you been able to complete the exercises you were given at the last visit?
8. Quality assurance
   A specific trial Case Report Form will need to be completed for each patient for each treatment contact, in order to accurately record all details of the interventions delivered to the patient.

5. Additional optional components

The following can be included in the patients care if the treating physiotherapist feels it is appropriate but must be recorded on the patients Case Report Form:

- ✓ **Manual Therapy**
  Hip joint mobilisations e.g. distraction, distraction with flexion, AP glides. Trigger point work.
- ✓ **Hip Joint Injection**
  Potentially useful for patients who do not improve with 'core' treatment. Maximum of one steroid hip injection allowed.
- ✓ **Orthotics**
  Patients can be assessed for biomechanical abnormalities and either have these corrected by the treating physiotherapist. Alternatively patients can be referred to allied health care professionals such as a podiatrist for custom made insoles etc.
- ✓ **Taping**
  Taping techniques such as taping the thigh into external rotation and abduction to help with postural modification/reminding.
- ✓ **Group-based treatments**
  The core programme can be supplemented by but must **NOT** be substituted with group based treatment.
- ✓ **Treatment of additional pathology/symptoms**
  Physiotherapists are free to treat any additional pathology or symptoms that they feel is exacerbating a patient's FAI. Examples of this might include treating co-existing low back pain.

6. Protocol exclusions

- ✘ **Forceful manual techniques**
  Forceful manual techniques in restricted range of movement (Grade V mobilisations, or forceful stretching). No painful hard end stretches.
- ✘ **Student or technical instructor care**
  Care should not be delivered by a student or technical instructor
- ✘ **Hydrotherapy**
  Patients should not have hydrotherapy as part of their treatment
- ✘ **Acupuncture**
  Patients should not have acupuncture as part of their treatment
- ✘ **Electrotherapy**
  Patients should not have electrotherapy as part of their treatment

7. Comments and Suggestions

Please email the UK FASHIoN Team on ukfashion@warwick.ac.uk with any queries, comments or suggestions.

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Personalised Hip Therapy Core Exercises

FASHION
STUDYING HIP IMPINGEMENT

PERSONALISED HIP THERAPY

Exercises

For Physiotherapist use only

Personalised Hip Therapy Core Exercises

1. Gym Ball Exercise

Description

- Practise sitting on the ball and gently moving your pelvis forwards and backwards, side to side and in circles.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

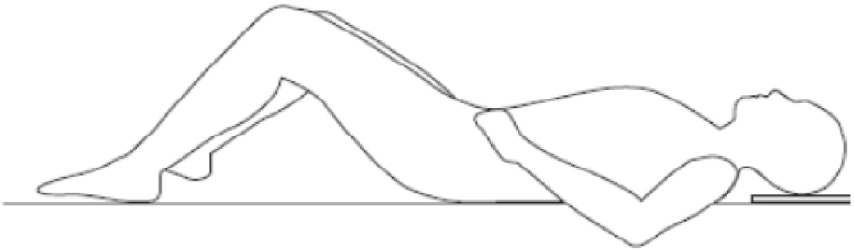
Additional information _____

Extra option 1

- Lift one foot from the floor whilst maintaining your balance and keeping good symmetrical posture on the ball.
- Relax and repeat on alternate legs.

Personalised Hip Therapy Core Exercises

2. Abdominal Exercise



Description

- On your back, draw the belly button down towards the spine
- Keep pelvis still and keep breathing!

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

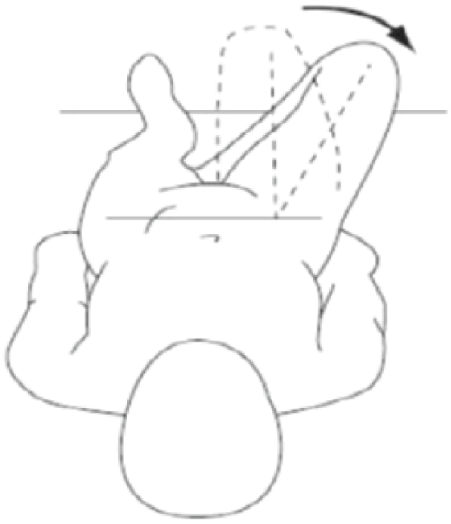
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

3. Stability Exercise q



Description

- Lie on back with legs bent, feet together and flat on the bed.
- Keep the lower back in neutral position throughout the exercise.
- Tighten the lower stomach muscles as described in abdominal exercise.
- Sustain throughout the exercise.
- Keeping the heel on the floor slowly let one hip roll out to the side.
- Only roll the leg as far as trunk control allows.
- Slowly return to the start position with control.
- Make sure that you keep the muscle at the front of your hip relaxed.
- Repeat on the opposite side
- Repeat ____ times on each leg.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

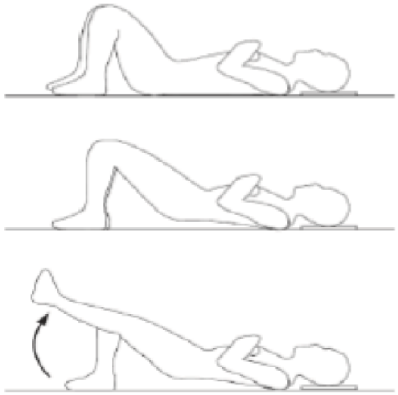
Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

FASHION
STUDYING HIP IMPINGEMENT

4. Stability Exercise r



Description

- Lie on the back with knees bent and feet slightly apart.
- Tighten the lower stomach muscles as described in abdominal exercise.
- Keeping the back flat slowly lift the pelvis until your knees, hips and shoulders are level.
- Hold this position for _____seconds, relax slowly.
- Repeat up to _____ times.
- You should feel your bottom and stomach muscles doing the work and not the hamstring muscles at the back of the thigh.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Extra option 1

- Same as above but when you have your bottom lifted try lifting one heel at a time from the bed whilst keeping your pelvis still.
- Hold this position for _____ seconds, relax slowly.
- Repeat up to _____ times.

Extra option 2

- Same as above but then shift the weight onto one foot and slowly straighten the other knee without side shifting or twisting the pelvis excessively.
- The knees should stay slightly apart.
- Slowly return to the start position with control.
- Hold this position for _____ seconds, relax slowly.
- Repeat up to _____ times.

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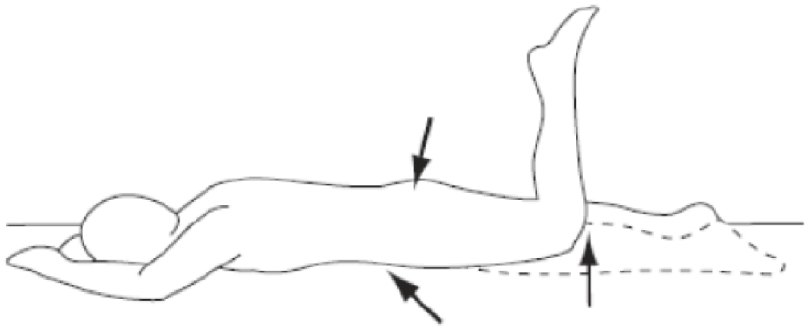
Personalised Hip Therapy Core Exercises

5. Stability Exercise t



Description

- Lie face down with hips and back relaxed and one knee bent.
- Tighten the lower stomach muscle and gently squeeze both buttocks to flatten the lower back.
- Hold this contraction and lift the bent leg 5cm.
- Do not let the back arch or pelvis twist.
- Hold for _____ seconds.
- Repeat _____ times on each leg.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

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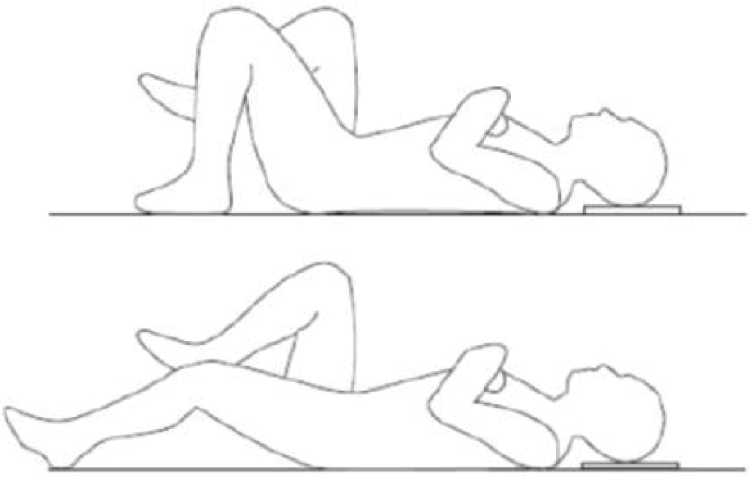
6. Stability Exercise o



Description

- Lie on back with legs bent, feet together and flat on the bed.
- Keep the lower back in a neutral position throughout the exercise.
- Tighten the lower stomach muscles as described in abdominal exercise and sustain throughout the exercise.
- Keeping the heel on the floor, slowly slide the leg out
- Only slide the leg as far as trunk control allows.
- Slowly return to the start position with control.
- Repeat on the opposite side.
- Repeat _____ times on each leg.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

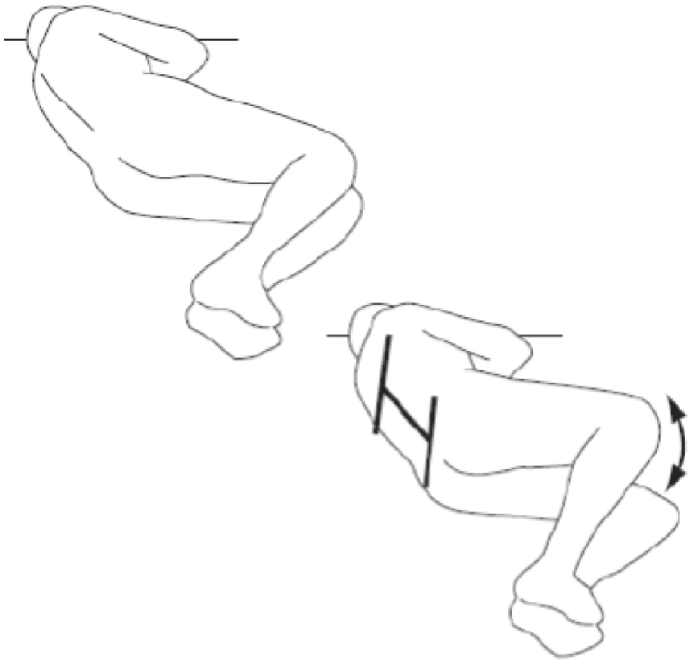
Frequency _____

Additional information _____

UKFASHIoN_PHT Core Exercises V2.0_18Jun14

Personalised Hip Therapy Core Exercises

7. Stability Exercise p / Clam



Description

- Lie on the side with pelvis square, the hips flexed to approximately 45 degrees and the knees bent.
- Tighten the lower stomach muscles as in exercise 1 to maintain the back to a neutral position throughout the exercise.
- Leaving the heels together slowly lift the top knee by turning the hip out without letting the back or pelvis twist.
- Only turn out as far as stable back and pelvis allow.
- Hold this position with minimal effort.
- Hold for ____ seconds
- Repeat ____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

FASHION
STUDYING HIP IMPINGEMENT

8. Stability Exercise s

Description

- Lie on your side with the pelvis square.
- The bottom leg is comfortably bent while the top leg is held straight.
- Tighten the lower stomach to keep the back in a neutral position throughout the exercise.
- Keep the knee facing forward / out.
- Lift the leg up and back slightly.
- Hold this position for a few seconds then slowly turn the leg back in.
- Only turn out as far as a stable back and pelvis allow.
- Hold for ____ seconds.
- Repeat ____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

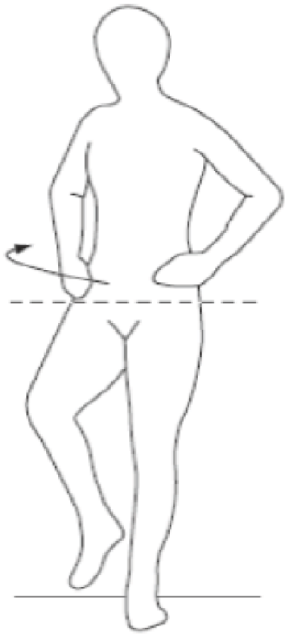
Frequency _____

Additional information _____

UKFASHIoN_PHT Core Exercises V2.0_18Jun14

Personalised Hip Therapy Core Exercises

9. Stability Exercise g



Description

- Stand tall with feet together and weight over the mid foot (do not let the pelvis sway forward).
- Gently squeeze both buttocks then slowly lift one foot behind you (5cms).
- Keep the shoulders and pelvis level
- Slowly turn body away from the weight bearing leg.
- Do not allow any forward or sideways tilt of the pelvis.
- Make sure the buttock on the weight bearing leg remains tight.
- Hold for _____ seconds.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

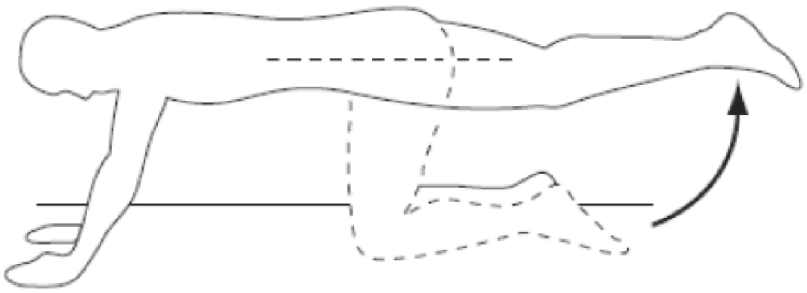
Frequency _____

Additional information _____

UKFASHIoN_PHT Core Exercises V2.0_18Jun14

Personalised Hip Therapy Core Exercises

10. Stability Exercise h



Description

- On hands and knees with the knees under the hips and the back relaxed in a neutral position.
- Keep the back controlled, slowly straighten the hip and knee to lift the leg out behind you.
- Contract the buttocks slightly during the leg lift.
- Do not let the back arch or twist.
- Only lift as far as the stable back allows.
- Hold for _____ seconds then lower slowly.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

11. Stability Exercise L/ Forward Lunge

Description

- Stand straight.
- Take a step forward and bend your knees.
- Return to the starting position.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

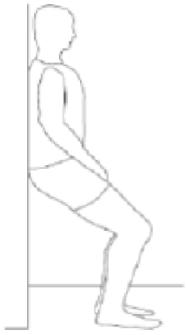
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

12. Stability Exercise z



Description

- In standing, back against a wall.
- Slide down wall about 6-8 inches.
- Keep back against the wall.
- Repeat _____ times.

Prescription

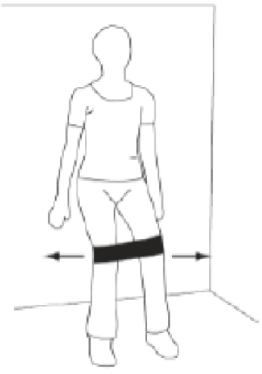
To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Extra option 1



- Place a theraband around your knees.
- Try to separate your knees against the resistance of the theraband. At the same time slide down wall about 6-8 inches and then relax the theraband.
- Repeat _____ times.

Personalised Hip Therapy Core Exercises

13. VMO Exercise

Description

- Lean sideways against the wall, standing on your operated leg.
- Bend the non-effected leg up against the wall in front of you.
- Use the non-effected leg to push against the wall while keeping your balance with the muscles of the operated leg.
- Hold for _____ seconds.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

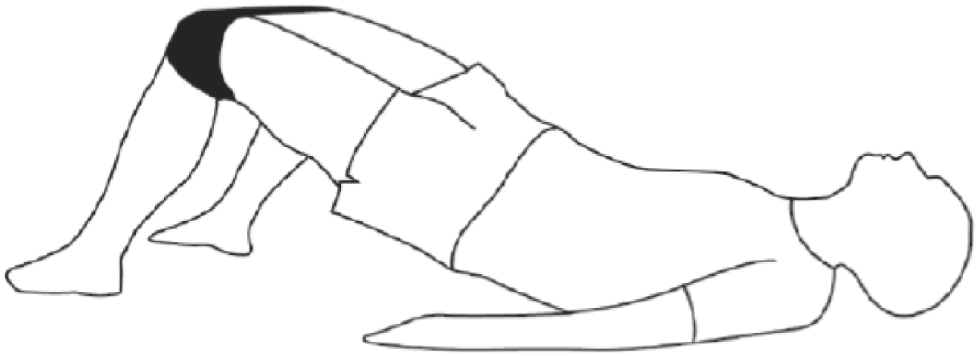
Additional information _____

Extra option 1

- Same as above
- Add in an exercise ball between the non-effected leg (knee) and the wall, while keeping your balance with the muscles of the operated leg.

Personalised Hip Therapy Core Exercises

14. VMO Exercise



Description

- Lie on your back, hip and knees bent, theraband around your knees
- Lift hips whilst keeping knees apart
- Lower keeping knees apart.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

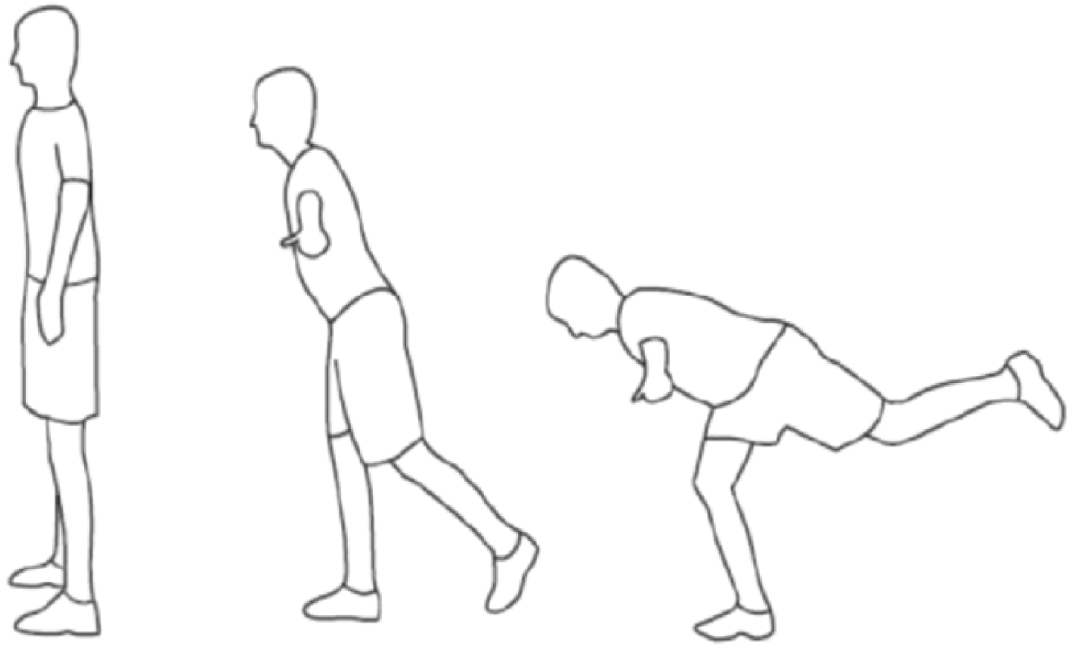
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

15. Inverted Hamstring Strength Exercise



Description

- Straight arms.
- Maintain core.
- Fully extend hip and knee.
- Hold for _____ seconds.
- Aim to do _____ repeats.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

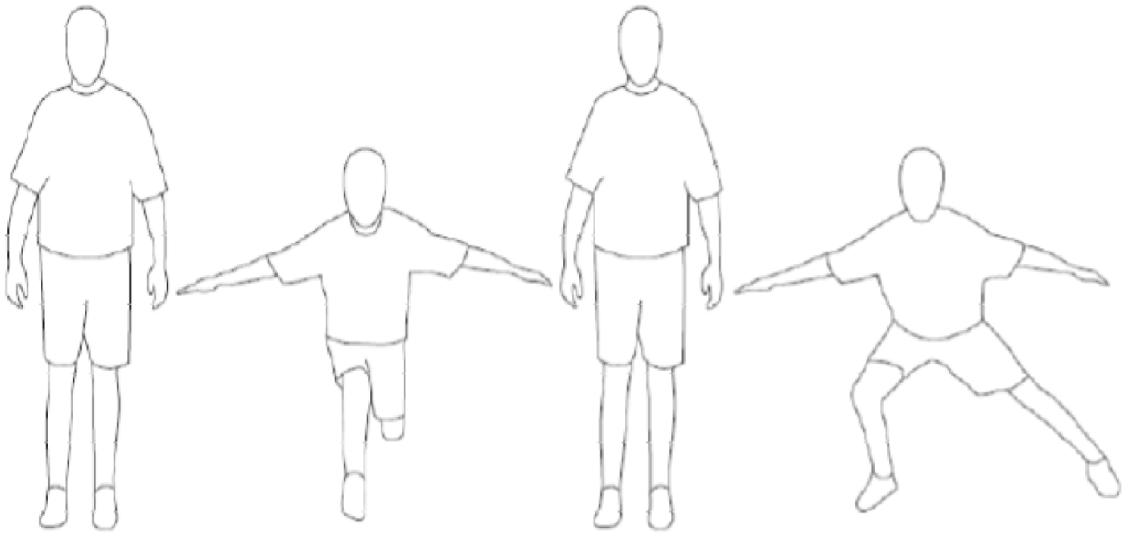
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

16. 3 Way Lunge Strength Exercise



Description

- From starting position, lunge forward, then straight backward then to side
- _____ times through, so in effect _____ toe touches on each leg

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

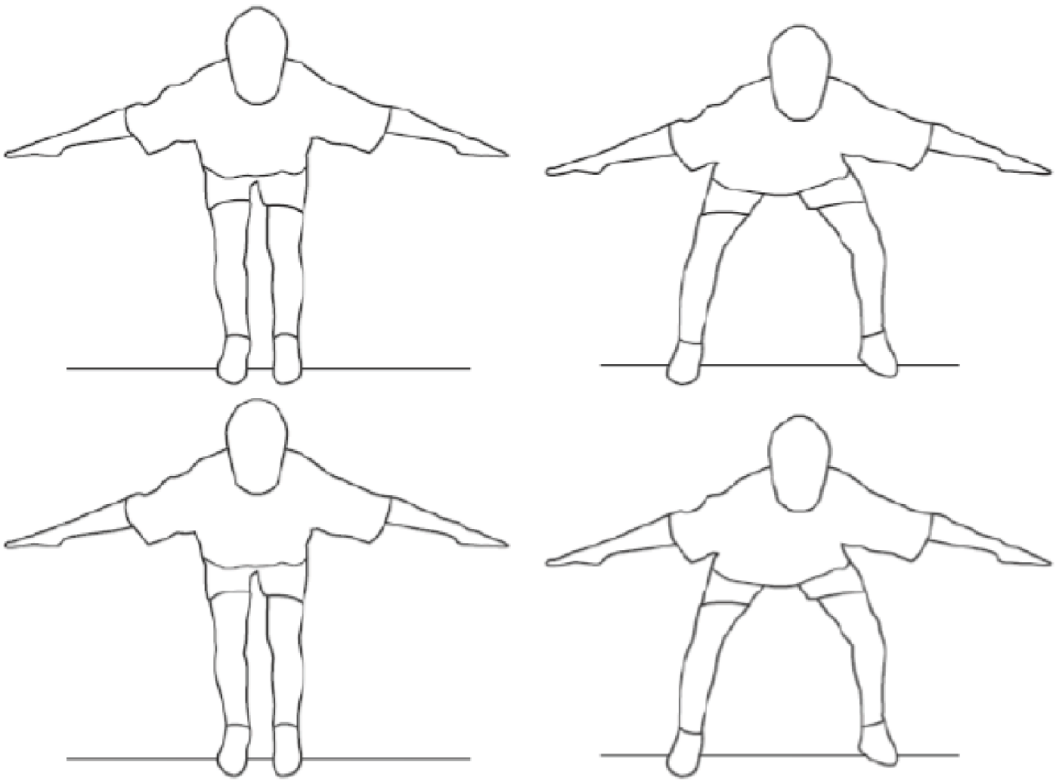
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

17. Crab Walk Strength Exercise



Description

- 15m long line
- Stay low in squat position
- Side step both directions

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

18. Gluteal Dip Strength Exercise

Description

- Stand on a raised stable surface, with a straight back.
- Stand on one leg, with the free leg straight and off the edge of the surface.
- Allow the free leg to dip down below the surface 5-10cm.
- Do the same on the other leg.
- Should feel "burn" in standing leg around the buttock area.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

19. Side Plank

Description

- Lying on your side, elbow of bottom arm on the floor, and top leg in front of bottom leg.
- Raise your hips up so that your spine is like a board.
- Do not let your legs sag down or backwards.
- Hold for _____ seconds.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

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20. Kneeling / Hip Flexor Stretching

Description

- Kneel on the floor with your trunk upright.
- Gently lean back at the waist until you feel a pull on the front of your thighs.
- Hold for _____ seconds.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

21. External Rotation Stretches

Description

- On your back with hips bent, place effected legs ankle onto opposite knee (as shown).
- Slowly bend non-effected hip and feel pull in buttock.
- Hold for _____seconds.
- Repeat _____ times.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

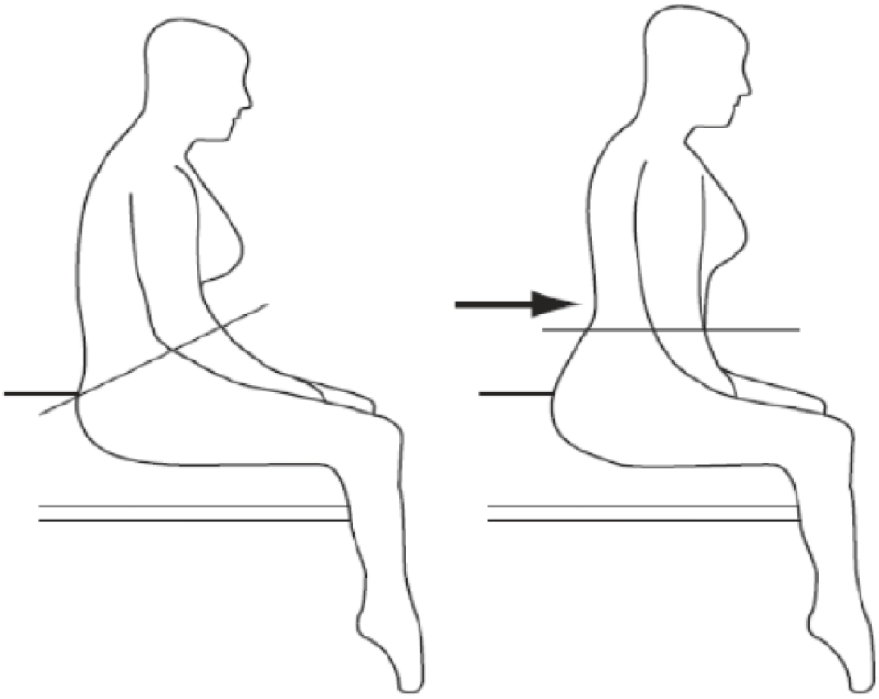
Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

22. Pelvic tilt exercises



Description

- Sit comfortably with knees bent over the edge of a chair or table
- Allow abdominal, pelvic and lower back muscles to relax
- Then tighten the lower back and pelvis muscles in order to exaggerate the lumbar curvature of the lower back and bring the pelvis into a more upright position (see second diagram).
- Hold for _____ seconds
- Then relax back

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

23. Anterior capsule hip joint mobilisations

Description

- Patient lying prone
- You may place a rolled up towel under thigh to bring hip into slight extension
- Place hand over the posterior aspect of the greater trochanter
- You may need to flex the knee to wind up rectus femoris and tighten anterior capsule (second diagram).
- Use your hand to push and mobilise the femoral head in a posterior anterior direction.
- N.B You can add in external rotation to wind the anteromedial capsule up before applying the posterior anterior mobilisation.

Prescription

Not applicable

Personalised Hip Therapy Core Exercises

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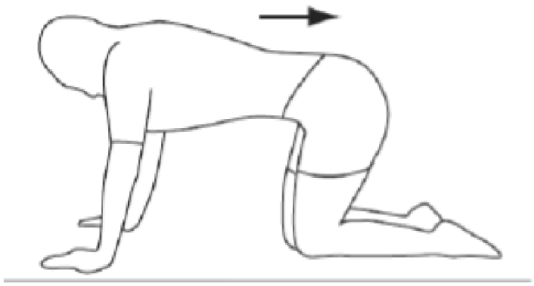
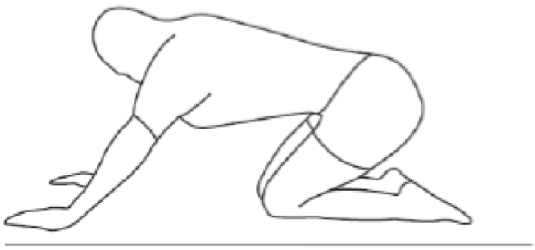
24. Hip joint glides





Description

- On all fours with arms and thighs vertical
- Gently rock backwards so that arms are in front and the knees bend
- Rock backwards as far as is comfortable and hold for _____ seconds
- Return to starting position
- Repeat _____ times

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Personalised Hip Therapy Core Exercises

FASHION
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Notes

Diary

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

My Personalised Hip Therapy Diary

Name: _____

Physiotherapist: _____

Start Date: _____

This diary is for you to keep a record of the hip exercises that you do, as advised by your physiotherapist.

It is to help you and your physiotherapist see if you are managing to complete your exercises, so it works best if you are honest.

THERE ARE NO RIGHT OR WRONG ANSWERS

Version 1.0 | 20/02/2014

Instructions

Please:

1. Try and fill your diary in regularly
2. Every time you complete a set of hip exercises place a tick in the appropriate box.
3. Record how hard you felt the exercises were (using the scale on the next page)
4 There is a comments box for you to write any thoughts or feelings you have each day. For example, you could record if the exercises are becoming easier, or if you find any exercises particularly difficult.

If you did not manage to complete any exercises that day you can note why, any your physiotherapist can help you to work around any obstacles you uncover.

Below is an example of what part of a week might look like:

	Sets of each exercise completed (please tick)						How the exercise feel	Comments
	Exs 1	Exs 2	Exs 3	Exs 4	Exs 5	Exs 6		
Monday	✓ ✓	✓	✓ ✓	✓ ✓	✓ ✓	✓ ✓	5	*Exercise 1 was easy, 2 was difficult*

"How the exercises feel" scale

1. Very, very easy/no problem
2. Very easy
3. Fairly easy
4. **Moderate/beginning to feel hard**
5. **Fairly Hard**
6. **Hard**
7. Very Hard
8. Very, very hard
9. Extremely hard
10. Maximum

The exercises should feel between level 4 ("moderate/beginning to feel hard") and level 6 ("Hard"). Below this you are not getting the maximum benefit and above this you are working harder than you need to.

REMEMBER

- **It is very important to build up your exercises gradually**
- **Work at a level/pace that is right for you**
- **After, exercise, it is normal to experience some discomfort around your hip and in the surrounding muscles, and this may last for a couple of days. BUT, if the discomfort is severe or lasts for longer than this, reduce your exercises and contact your physiotherapist.**

Week commencing: ……/……/……

	Sets of each exercise completed (please tick)						How the exercise feels	Comments
	Exs 1	Exs 2	Exs 3	Exs 4	Exs 5	Exs 6		
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Appendix 2 Results

Recruitment: randomisation by site

TABLE 36 Randomised patients summarised by treatment group and centre

Site	Treatment group, *n*		
	Surgery (*N* = 171)	PHT (*N* = 177)	Total (*N* = 348)
University Hospitals Coventry and Warwickshire	37	41	78
Yeovil District Hospital	11	11	22
Royal Devon and Exeter Hospital	9	9	18
Royal Orthopaedic Hospital	20	19	39
Wrightington Hospital	6	6	12
The Royal Cornwall	3	4	7
Elective Orthopaedic Centre	1	1	2
Northumbria Healthcare NHS Foundation Trust	7	7	14
The Royal London	2	3	5
Doncaster and Bassetlaw Teaching Hospital NHS Foundation Trust	8	8	16
Royal National Orthopaedic Hospital	5	5	10
Frimley Park Hospital	11	12	23
The Robert Jones and Agnes Hunt Orthopaedic Hospital	16	16	32
South Tees Hospitals NHS Foundation Trust	5	3	8
University College Hospital	4	4	8
Guys' and St Thomas' Hospital	6	5	11
Cardiff and Vale Hospitals	5	6	11
Glasgow Royal Infirmary	3	2	5
Wrexham Maelor Hospital	1	3	4
King's College Hospital	7	6	13
North Bristol NHS Trust	3	4	7
Spire Manchester Hospital	1	2	3
Total	171	177	348

TABLE 37 Randomised patients summarised by randomisation strata (recruiting site and FAI type)

Site	FAI type, *n*					
	Cam		Mixed		Pincer	
	Surgery (*N* = 171)	PHT (*N* = 177)	Surgery (*N* = 171)	PHT (*N* = 177)	Surgery (*N* = 171)	PHT (*N* = 177)
University Hospitals Coventry and Warwickshire	34	36	1	2	2	3
Yeovil District Hospital	8	8	2	2	1	1
Royal Devon and Exeter Hospital	6	6	3	3	0	0
Royal Orthopaedic Hospital	16	14	4	3	0	2
Wrightington Hospital	6	6	0	0	0	0
The Royal Cornwall	3	3	0	1	0	0
Elective Orthopaedic Centre	1	1	0	0	0	0
Northumbria Healthcare NHS Foundation Trust	6	7	1	0	0	0
The Royal London	2	3	0	0	0	0
Doncaster and Bassetlaw Teaching Hospital NHS Foundation Trust	3	2	4	5	1	1
Royal National Orthopaedic Hospital	3	0	2	5	0	0
Frimley Park Hospital	8	8	1	3	2	1
The Robert Jones and Agnes Hunt Orthopaedic Hospital	10	12	3	2	3	2
South Tees Hospitals NHS Foundation Trust	2	3	2	0	1	0
University College Hospital	2	2	3	1	0	0
Guys' and St Thomas' Hospital	4	5	1	0	1	0
Cardiff and Vale Hospitals	3	4	1	1	1	1
Glasgow Royal Infirmary	3	1	0	0	0	1
Wrexham Maelor Hospital	1	1	0	1	0	1
King's College Hospital	5	5	1	0	1	1
North Bristol NHS Trust	3	2	0	2	0	0
Spire Manchester Hospital	1	2	0	0	0	0
Total	130	131	29	31	13	14

TABLE 38 Withdrawal details summarised by treatment group

Type of withdrawal	Treatment group, *n* (%)		Total (*N* = 348), *n* (%)
	Surgery (*N* = 171)	PHT (*N* = 177)	
Participant requested to withdraw from trial			
Yes	13	18	31
No	158	159	317
Patient level of withdrawal			
From treatment only	9 (69)	12 (67)	21 (68)
From treatment and follow-up	3 (23)	4 (22)	7 (23)
Missing	1 (8)	2 (11)	3 (10)
Participant reason for withdrawal			
Participant's decision	2 (15)	3 (17)	5 (16)
Participant does not want to continue with treatment	8 (62)	9 (50)	17 (55)
No reason given	0 (0)	1 (6)	1 (3)
Patient does not want to complete questionnaire	0 (0)	3 (17)	5 (16)
Other reason	2 (15)	3 (17)	3 (10)
Missing	1 (8)	2 (11)	3 (10)

Surgery

TABLE 39 Hip arthroscopy procedure details (for those who received surgery)

Key stage of procedure undertaken	Hip arthroscopy (*N* = 144), *n* (%)
General anaesthetic with muscle relaxation	
Yes	140 (97)
No with reason	3 (2)
Missing	1 (1)
Supine or lateral patient positioning	
Yes	143 (99)
No with reason	0 (0)
Missing	1 (1)
Operating table used with facility for traction and range of movement testing	
Yes	143 (99)
No with reason	0 (0)
Missing	1 (1)

continued

TABLE 39 Hip arthroscopy procedure details (for those who received surgery) (*continued*)

Key stage of procedure undertaken	Hip arthroscopy (*N* = 144), *n* (%)
Arthroscopy of central compartment	
Yes	141 (98)
No with reason	0 (0)
Missing	3 (2)
Arthroscopy of peripheral compartment	
Yes	140 (97)
No with reason	0 (0)
Missing	4 (3)
Entire acetabular labrum examined	
Yes	142 (99)
No with reason	1 (1)
Missing	1 (1)
Entire articular surface examined	
Yes	142 (99)
No with reason	1 (1)
Missing	1 (1)
Confirmed impingement has been relieved using either range of movement testing or an image intensifier	
Yes	138 (96)
No with reason	4 (3)
Missing	2 (1)
Did the patient have any intraoperative complications (e.g. fracture, iatrogenic)?	
Yes	4 (3)
No with reason	135 (94)
Missing	5 (3)
Was standard postoperative rehabilitation/physiotherapy prescribed for this patient?	
Yes	141 (98)
No with reason	2 (1)
Missing	1 (1)

Postoperative rehabilitation protocols

Twenty of the 21 sites responded to the request for information about postoperative rehabilitation protocols. Eighteen (90%) sites had a protocol in place and two (10%) sites had no specific protocol but delivered 'usual-care' physiotherapy.

Four themes emerged from the protocols:

1. Seven (25%) sites delivered a prescriptive format adherent to a timeline according to postoperative weeks. Three (15%) sites adopted the Villar Bajwa protocol.[86]
2. Four (20%) sites used a phased rehabilitation programme for which there was an entry criteria stipulated for each level. These phases were described as early (immediate postoperative), intermediate and advanced rehabilitation.
3. Seven (35%) sites offered an additional phase of sport-specific training.
4. Two (10%) sites delivered a prescriptive early immediate postoperative phase. This phase was a continuation to usual care and was left to the discretion of the treating physiotherapist.

Personalised hip therapy

TABLE 40 Personalised hip therapy session details (for those who attended at least one PHT session)

PHT session detail	PHT sessions[a] (*N* = 947)
Number of sessions	891
Length of consultation (minutes)	
Mean	30
SD	11
Median	30
Minimum	0
Maximum	60
Type of session, *n* (%)	
Face to face	878 (93)
Telephone	31 (3)
E-mail	4 (1)
Missing	34 (3)
Assessment/reassessment, *n* (%)	
Ticked	834 (88)
Not ticked	102 (11)
Education and advice, *n* (%)	
Ticked	729 (77)
Not ticked	203 (21)
Help with pain relief, *n* (%)	
Ticked	696 (74)
Not ticked	235 (25)
Supervised exercises in clinic, *n* (%)	
Ticked	741 (78)
Not ticked	191 (20)
Exercise prescription given, *n* (%)	
Ticked	566 (60)
Not ticked	366 (39)

continued

TABLE 40 Personalised hip therapy session details (for those who attended at least one PHT session) (*continued*)

PHT session detail	PHT sessions[a] (*N* = 947)
Exercise diary given/reviewed, *n* (%)	
Ticked	399 (42)
Not ticked	491 (52)
Diary forgotten	39 (4)
Diary lost	0 (0)

a Where totals within a variable do not sum to 100% this indicates that data are missing.

TABLE 41 Exercises delivered during PHT sessions, by frequency

Number and type of exercise	Frequency, *n*
Other	671
Stability exercise r	337
Stability exercise p/clam	326
Stability exercise q	226
Stability exercise s	186
Stability exercise t	172
Abdominal exercise	170
Kneeling/hip flexor stretching	157
External rotation stretches	142
Pelvic tilt exercises	129
Stability exercise h	127
Stability exercise l/lunge	121
Stability exercise o	117
Gluteal dip strength	81
Stability exercise z	78
Hip joint glides	78
Crab walk strength	76
Side plank	75
Inverted hamstring strength	72
Gym ball exercise	69
Three-way lunge strength	48
VMO exercise	46
VMO exercise	45
Stability exercise g	38
Anterior capsule hip joint mobilisation	16

VMO, vastus medialis oblique.

Follow-up completeness of data

TABLE 42 Data completeness of outcome measures at baseline and at 6 and 12 months

iHOT-33 item	Number missing		
	Baseline ($N = 348$)	6 months ($N = 315$)	12 months ($N = 321$)
Compulsory item, *n*			
Hip ache	1	0	1
Hip stiffness from sitting all day	2	2	1
Long-distance walk difficulty	1	1	1
Hip pain while sitting	3	0	1
Standing on feet trouble	1	3	2
Getting off the floor difficulty	2	0	1
Walking on uneven floor	1	0	1
Lying on affected hip difficulty	2	1	2
Stepping over objects trouble	2	3	1
Climbing up stairs	5	0	1
Rising from sitting position	4	1	4
Long-stride discomfort	4	1	2
Getting out of a car trouble	1	0	1
Grinding, catching or clicking	6	1	5
Taking off socks, shoes and stockings	2	0	1
Overall pain in hip	6	1	1
Concern about fitness level	3	2	5
Post-activity hip pain	3	4	8
Concern about pain from sport	1	5	6
Quality-of-life deterioration	1	5	6
Performance level during sport	3	9	10
Frustration because of your hip	4	6	0
Distraction because of hip	4	5	0
Tension and stress relief difficulty	4	6	0
Discouragement as a result of your hip	6	7	3
Awareness of hip disability	5	5	0

continued

TABLE 42 Data completeness of outcome measures at baseline and at 6 and 12 months (*continued*)

iHOT-33 item	Number missing		
	Baseline (*N* = 348)	6 months (*N* = 315)	12 months (*N* = 321)
Non-compulsory item, *n*/*N*[a]			
Changing direction during sport	3/245	0/223	0/231
Heavy objects at work	0/207	0/178	0/198
Crouching or squatting trouble	5/320	4/266	2/280
Concern about job worsening hip pain	7/320	5/266	0/280
Reduced hip mobility difficulty at work	8/320	4/266	0/280
Sexual activity as a result of hip	0/311	0/279	0/284
Carrying children concerns	0/234	0/193	1/209
SF-12 item, *n*	*N* = 348	*N* = 291	*N* = 278
General health	1	1	0
Moderate activities	1	0	0
Climbing stairs	1	0	0
Accomplished less physical health	2	0	1
Limited activities	4	0	1
Accomplished less emotional problems	2	0	1
Did not do work or activities carefully	4	2	4
Pain interference with normal work	1	3	1
Calm and peaceful	0	3	1
Lot of energy	0	3	1
Downhearted and blue	0	4	1
Social activities	0	3	1
EQ-5D-5L item, *n*	*N* = 348	*N* = 293	*N* = 302
Mobility	0	0	0
Self-care	0	0	0
Usual activities	0	0	0
Pain	0	1	0
Anxiety	0	0	0
VAS	1	3	7

a Item considered missing if the 'not applicable' box had not been ticked and, therefore, a response was expected.

Appendix 3 Health economics

TABLE 43 Unit cost of operating room/surgery staff

Resource category	Sample ($n = 40$)			
	Mean (SE)	Unit cost (£)	Unit	Source of unit cost
Theatre time (hours)	2.09 (0.08)	298.68	Hour	ISD Scotland (2016)[54]
Inpatient length of stay (days)	1.57 (0.09)	332.77	Day	Reference costs (2016)[77]
Clinical staff				
Consultant surgeon	1.00 (0.00)	137	Hour	PSSRU 2016, section 15[52]
Consultant anaesthetist	1.00 (0.00)	135	Hour	PSSRU 2016, section 15[52]
Assistant surgeon	1.00 (0.07)	59	Hour	PSSRU 2016, section 15[52]
Radiographer (band 6)	0.95 (0.05)	46.00	Hour	PSSRU 2016, p. 221[52]
Nurse (band 6)	0.86 (0.10)	44.00	Hour	PSSRU 2016, section 14[52]
Nurse (band 5)	0.81 (0.09)	35	Hour	PSSRU 2016, section 14[52]
ODP (band 4)	1.07 (0.07)	30.00	Hour	PSSRU 2016, p. 221[52]
Health-care assistant (band 4)	1.20 (0.09)	28.00	Hour	PSSRU 2016, section 14[52]
Anaesthesia				
Propofol (Aspen Pharma Trading Ltd, Dublin, Ireland) 10-mg/ml amp (1% emulsion)	1	2.94	Per item	BNF 2016[58]
Rocuronium (Bowmed Ibisqus Ltd, Brynkinallt, UK) 10 mg/ml, 10-ml vial	2	5.79	Per item	BNF 2016[58]
Cyclizine 50 mg/ml, 1-ml amp	1	2.57	Per item	Prescription costs analysis database 2016[53]
Dexamethasone 3.8 mg/ml, 1-ml vial	2	1.49	Per item	Prescription costs analysis database 2016[53]
Cefuroxime 1.5-g vial	1	5.05	Per item	Prescription costs analysis database 2016[53]
Sugammadex [Merck Sharp & Dohme (UK) Ltd, Hoddesdon, UK] 100-mg/ml vial	1	59.64	Per item	BNF 2016[58]
Desflurane o2/w20	2	11.96	Per item	Shepherd *et al.*[87]
Hartmann's solution 1000 mls	1	6.80	Per item	Prescription costs analysis database 2016[53]
Fentanyl	1	4.99	Per item	Prescription costs analysis database 2016[53]
Paracetamol infusion (B. Braun Medical Ltd, Sheffield, UK) 10 mg/ml	1	1.20	Per item	BNF 2017[88]

ODP, operating department practitioner; PCA, prescription cost analysis.

TABLE 44 Unit cost of disposal surgical equipment

Equipment/implant	Quantity ($N = 40$), mean (SE)	Unit cost (£)	Supplier number	Source
Smith & Nephew				
Ligament chisel (radio-frequency probe)	0.100 (0.048)	340.79	72200682	*NHS Supply Chain Catalogue 2016*[56]
Ablator (radio-frequency probe)	0.650 (0.105)	340.79	72200683	
Tac-s (radio-frequency probe)	0.125 (0.053)	349.31	72200681	
Hook (radio-frequency probe)	0.125 (0.053)	149.32	7209646	
Incisor plus elite shaver	0.075 (0.042)	104.92	72200081	
4.5-mm-long curved shaver	0.200 (0.082)	137.25	7205332	
4.0/5.5-mm abrader burr	0.175 (0.071)	161.47	72200082	
4.0/5.5-mm flat top burr	0.025 (0.025)	161.47	72203130	
4.0/5.5-mm barrel burr	0.200 (0.073)	161.47	72203132	
ACCU-PASS suture	0.225 (0.076)	104.29	7210425	
All suture cefix	0.125 (0.089)	255.93	72201993	
Banana blade	0.150 (0.057)	35.00	72203307	
Ambient super multivac 50	0.075 (0.042)	167.07	ASHA4830-01	
Hip pac	0.025 (0.025)	38.56	7209874	
Dyonics water pump	0.075 (0.042)	66.95	7211006	
STARVAC 90	0.025 (0.025)	142.27	ASC4251-01	
SUPER TURBOVAC 90	0.050 (0.035)	154.64	ASH4250-01	
Hip disposable needle	0.025 (0.025)	96.52	72201811	
110-mm hip cannula	0.050 (0.035)	40.60	72200436	
Cross 50	0.025 (0.025)	139.05	72202140	
Arthrex (Naples, FL, USA)				
CoolCut™ ablator 90	0.100 (0.048)	123.04	AR-9705A-90	*NHS Supply Chain Catalogue 2016*[56]
CoolCut™ ablator 30/50	0.025 (0.025)	125.45	AR-9703A-90	
4.2-mm bone cutter (Excalibur)	0.025 (0.025)	77.20	AR-6420EX	
4.2-mm bone cutter	0.050 (0.035)	90.46	AR-6420XBC	
4.2-mm sabre tooth shaver	0.025 (0.025)	77.20	AR-6420CST	
4.2-mm dissector	0.025 (0.025)	90.46	AR-6420XDS	
4-mm burr	0.250 (0.069)	77.20	AR-8550RBE	
ConMed Linvatec (Utica, NY, USA)				
4.2-mm great white shaver	0.025 (0.025)	81.35	HPS-C001	*NHS Supply Chain Catalogue 2016*[56]
4.2-mm full radius resector	0.050 (0.035)	193.86	C9144	
4.5/5.5-mm spherical burr	0.050 (0.035)	193.86	C9014	
4.5/5-mm oval burr	0.050 (0.035)	59.12	702139600	

TABLE 44 Unit cost of disposal surgical equipment (*continued*)

Equipment/implant	Quantity ($N = 40$), mean (SE)	Unit cost (£)	Supplier number	Source
Stryker Corporation (Kalamazoo, MI, USA)				
5-mm resector	0.100 (0.048)	86.60	385552000	*NHS Supply Chain Catalogue 2016*[56]
5.5-mm pear burr	0.075 (0.055)	94.39	5820016050	
5.5-mm barrel burr	0.100 (0.048)	94.39	5820017050	
4.5-mm burr	0.025 (0.025)	86.60	375941000	
Pivot SlingShot	0.025 (0.025)	120.00	CAT02589	
Pivot NanoPass®	0.050 (0.035)	120.00	CAT02298	
Pivot InJector®	0.025 (0.025)	95.00	CAT01857	
Pivot CinchLock® SS	0.225 (0.121)	230.00	CAT02462	
Pivot NanoTack	0.100 (0.070)	200.00	CAT01858	
Samurai blade	0.050 (0.035)	124.21	CAT00227	
MicroFX blade	0.025 (0.025)	151.60	234-200-200	
Other manufacturer				
JuggerKnot® (Zimmer Biomet, Warsaw, IN, USA)	0.075 (0.075)	173.00	912068	*NHS Supply Chain Catalogue 2016*[56]

TABLE 45 Patient-reported health service use

	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Baseline								
Inpatient stay (days)								
Orthopaedics (hip/leg)	1.2	91.8	0.071 (0.022)	0.6	89.3	0.105 (0.022)	−0.034 (−0.158 to 0.040)	0.248
Orthopaedics (other)	1.2	98.8	0.000 (0.000)	0.6	98.9	0.006 (0.006)	−0.006 (−0.028 to 0.000)	
Rehabilitation unit	1.2	98.8	0.000 (0.000)	0.6	98.9	0.006 (0.006)	−0.006 (−0.028 to 0.000)	
Day case	1.2	94.7	0.041 (0.013)	0.6	97.7	0.017 (0.013)	0.024 (−0.014 to 0.097)	0.162
Pain injection	1.2	98.2	0.006 (0.006)	0.6	98.9	0.006 (0.006)	0.000 (−0.027 to 0.029)	0.876
Other inpatient stay[a]	1.2	96.5	0.024 (0.016)	0.6	96.6	0.04 (0.016)	−0.016 (−0.100 to 0.041)	0.452
Outpatient attendance								
Orthopaedics (hip/leg)	1.2	43.3	1.047 (0.09)	1.1	41.2	1.074 (0.088)	−0.027 (−0.481 to 0.427)	0.84
Physiotherapy (hip/leg)	1.2	90.6	0.219 (0.078)	1.1	88.7	0.291 (0.076)	−0.072 (−0.492 to 0.219)	0.532
Physiotherapy (other)	1.2	97.7	0.018 (0.018)	1.1	96.6	0.04 (0.018)	−0.022 (−0.123 to 0.040)	0.368
Accident and emergency	1.2	94.7	0.047 (0.02)	1.1	94.9	0.051 (0.019)	−0.004 (−0.095 to 0.076)	0.86
Radiology (number of scans)	1.2	95.3	0.047 (0.02)	1.1	93.8	0.057 (0.02)	−0.010 (−0.097 to 0.070)	0.698
Other outpatient attendance[b]	1.2	88.9	0.207 (0.074)	1.1	89.3	0.229 (0.073)	−0.021 (−0.350 to 0.290)	0.842

	Treatment group							
	Surgery ($n = 171$)			PHT ($n = 177$)			Surgery vs. PHT	
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Primary health-care contact (minutes)								
GP surgery	1.2	64.3	31.585 (14.972)	1.1	58.8	9.205 (14.713)	22.380 (−3.255 to 112.987)	0.268
GP home visit	1.2	98.8	0.000 (0.000)	1.1	98.9	0.000 (0.000)	0.000 (0.000 to 0.000)	
GP telephone	1.2	90.6	0.995 (0.671)	1.1	94.4	1.286 (0.66)	−0.290 (−3.640 to 1.744)	0.842
Practice nurse	1.2	95.9	2.426 (1.51)	1.1	94.9	0.671 (1.484)	1.755 (−1.412 to 10.429)	0.676
District nurse	1.2	98.8	0.000 (0.000)	1.1	98.3	0.114 (0.114)	−0.114 (−0.572 to 0.000)	
Community physiotherapy	1.2	96.5	1.746 (3.087)	1.1	92.1	10.343 (3.033)	−8.597 (−27.504 to −2.263)	0.01
Other primary care[c]	1.2	95.9	3.728 (2.062)	1.1	96.6	3.434 (2.026)	0.294 (−8.669 to 9.443)	0.962
Social care contacts (minutes)								
Community physiotherapy	1.8	98.2	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Home care worker	1.8	97.7	1.786 (1.770)	0.6	99.4	0.000 (0.000)	1.786 (0.000 to 9.186)	0.724
Other social care[d]	1.8	98.2	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Medications (item)								
Medications	3.5	63.7	13.77 (2.511)	0.6	71.8	11.528 (2.431)	2.241 (−7.168 to 15.641)	0.536
Aids and adaptations (per item/pair where appropriate)								
Crutches	2.3	95.3	0.036 (0.018)	0.6	97.7	0.028 (0.018)	0.008 (−0.065 to 0.085)	0.738
Stick	2.3	97.1	0.006 (0.006)	0.6	99.4	0.000 (0.000)	0.006 (0.000 to 0.031)	0.722
Grab rail	2.3	97.1	0.006 (0.006)	0.6	99.4	0.000 (0.000)	0.006 (0.000 to 0.031)	0.71
Dressing aids	2.3	97.7	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other aids and adaptations[e]	2.3	97.7	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	

continued

TABLE 45 Patient-reported health service use (*continued*)

	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
6 months post randomisation								
Inpatient stay (days)								
Orthopaedics (hip/leg)	17.0	56.7	0.669 (0.164)	22.0	71.8	0.17 (0.167)	0.499 (0.224 to 1.588)	0.002
Orthopaedics (other)	17.0	82.5	0.014 (0.011)	22.0	77.4	0.007 (0.011)	0.007 (–0.033 to 0.070)	0.918
Rehabilitation unit	17.0	81.3	0.021 (0.051)	22.0	77.4	0.072 (0.052)	–0.051 (–0.332 to 0.063)	0.674
Day case	17.0	82.5	0.007 (0.009)	22.0	76.8	0.014 (0.009)	–0.007 (–0.055 to 0.027)	0.468
Pain injection	17.0	83.0	0.000 (0.000)	22.0	77.4	0.007 (0.006)	–0.007 (–0.037 to 0.000)	
Other inpatient stay[a]	17.0	80.7	0.035 (0.017)	22.0	78.0	0.000 (0.000)	0.035 (0.011 to 0.118)	0.038
Outpatient attendance								
Orthopaedics (hip/leg)	17.5	52.0	0.943 (0.237)	22.0	65.5	0.623 (0.239)	0.320 (–0.594 to 1.546)	0.33
Physiotherapy (hip/leg)	17.5	56.1	1.816 (0.284)	22.0	47.5	2.217 (0.287)	–0.402 (–2.036 to 0.685)	0.356
Physiotherapy (other)	17.5	79.5	0.113 (0.073)	22.0	73.4	0.181 (0.074)	–0.068 (–0.448 to 0.184)	0.492
Accident and emergency	17.5	80.1	0.043 (0.021)	22.0	75.1	0.036 (0.021)	0.006 (–0.067 to 0.105)	0.91
Radiology (number of scans)	17.5	80.7	0.028 (0.016)	22.0	77.4	0.014 (0.016)	0.014 (–0.049 to 0.090)	0.584
Other outpatient attendance[b]	17.5	77.2	0.135 (0.046)	22.0	71.8	0.123 (0.046)	0.012 (–0.166 to 0.222)	0.876

	Treatment group							
	Surgery ($n = 171$)			PHT ($n = 177$)			Surgery vs. PHT	
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Primary health care contact (minutes)								
GP surgery	17.5	50.9	10.839 (2.523)	20.9	58.8	9.752 (2.532)	1.087 (−10.726 to 12.721)	0.732
GP home visit	17.5	81.9	0.142 (0.129)	20.9	79.1	0.000 (0.000)	0.142 (0.000 to 0.752)	0.758
GP telephone	17.5	76.0	1.28 (0.534)	20.9	75.7	0.88 (0.535)	0.400 (−1.907 to 3.001)	0.56
Practice nurse	17.5	71.9	2.447 (0.66)	20.9	75.1	1.243 (0.662)	1.204 (−1.354 to 4.578)	0.2
District nurse	17.5	77.8	0.894 (0.401)	20.9	78.5	0.429 (0.403)	0.465 (−1.175 to 2.481)	0.39
Community physiotherapy	17.5	76.0	10.071 (3.013)	20.9	75.7	4.571 (3.024)	5.499 (−4.179 to 22.121)	0.192
Other primary care[c]	17.5	80.1	2.943 (2.898)	21.5	75.7	5.475 (2.919)	−2.532 (−17.518 to 8.329)	0.532
Social care contacts (minutes)								
Community physiotherapy	17.0	81.3	3.38 (2.054)	20.9	78.5	1.286 (2.069)	2.095 (−4.212 to 13.000)	0.524
Home care worker	17.0	83.0	0.000 (0.000)	20.9	79.1	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other social care[d]	17.0	83.0	0.000 (0.000)	20.9	79.1	0.000 (0.000)	0.000 (0.000 to 0.000)	
Medications (item)								
Medications	17.5	47.4	25.695 (3.945)	21.5	59.3	9.108 (3.973)	16.587 (9.738 to 43.725)	< 0.001
Aids and adaptations (per item/pair where appropriate)								
Crutches	18.1	57.3	0.564 (0.055)	22.6	75.7	0.036 (0.056)	0.528 (0.597 to 1.076)	< 0.001
Stick	18.1	80.7	0.021 (0.012)	22.6	76.8	0.007 (0.013)	0.014 (−0.024 to 0.084)	0.496
Grab rail	18.1	81.3	0.014 (0.013)	22.6	77.4	0.000 (0.000)	0.014 (0.000 to 0.074)	0.764
Dressing aids	18.1	77.8	0.214 (0.087)	22.6	77.4	0.000 (0.000)	0.214 (0.082 to 0.670)	
Other aids and adaptations[e]	18.1	80.1	0.036 (0.019)	22.6	77.4	0.000 (0.000)	0.036 (0.000 to 0.135)	0.114

continued

TABLE 45 Patient-reported health service use (*continued*)

	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
12 months post randomisation								
Inpatient stay (days)								
Orthopaedics (hip/leg)	14.6	69.6	0.73 (0.319)	23.7	67.8	0.134 (0.331)	0.596 (0.089 to 2.544)	0.002
Orthopaedics (other)	14.6	85.4	0.000 (0.000)	23.7	74.6	0.037 (0.019)	−0.037 (−0.140 to 0.000)	
Rehabilitation unit	14.6	84.8	0.007 (0.007)	23.7	75.7	0.007 (0.007)	−0.001 (−0.035 to 0.031)	0.712
Day case	14.6	81.3	0.048 (0.014)	23.7	75.7	0.007 (0.014)	0.041 (0.007 to 0.129)	0.03
Pain injection	14.6	84.8	0.007 (0.007)	23.7	75.7	0.007 (0.007)	−0.001 (−0.034 to 0.024)	0.676
Other inpatient stay[a]	14.6	83.6	0.021 (0.048)	23.7	72.9	0.141 (0.05)	−0.120 (−0.448 to 0.007)	0.062
Outpatient attendance								
Orthopaedics (hip/leg)	15.8	46.2	0.66 (0.069)	23.7	65.0	0.289 (0.072)	0.371 (0.264 to 0.898)	< 0.001
Physiotherapy (hip/leg)	15.8	52.0	2.611 (0.339)	23.7	61.0	0.822 (0.35)	1.789 (1.379 to 4.554)	< 0.001
Physiotherapy (other)	15.8	80.1	0.292 (0.114)	23.7	72.9	0.148 (0.118)	0.144 (−0.231 to 0.789)	0.39
Accident and emergency	15.8	81.3	0.035 (0.023)	23.7	70.1	0.096 (0.023)	−0.062 (−0.205 to 0.006)	0.072
Radiology (number of scans)	15.8	81.9	0.028 (0.014)	23.7	74.0	0.03 (0.014)	−0.002 (−0.070 to 0.058)	0.922
Other outpatient attendance[b]	15.8	77.8	0.139 (0.064)	23.7	63.8	0.333 (0.066)	−0.194 (−0.595 to -0.027)	0.028
Primary health-care contact (minutes)								
GP surgery	15.2	55.0	12.464 (2.226)	24.9	49.2	11.358 (2.324)	1.105 (−7.578 to 12.831)	0.774
GP home visit	15.2	84.8	0.000 (0.000)	24.9	75.1	0.000 (0.000)	0.000 (0.000 to 0.000)	
GP telephone	15.2	78.9	1.041 (0.694)	24.9	67.8	1.829 (0.724)	−0.787 (−5.120 to 1.515)	0.482
Practice nurse	15.2	78.9	2.069 (0.762)	24.9	69.5	1.695 (0.796)	0.373 (−2.493 to 4.121)	0.726
District nurse	15.2	82.5	0.586 (1.724)	24.9	72.3	4.173 (1.8)	−3.587 (−14.605 to 0.774)	0.16
Community physiotherapy	15.2	81.3	14.69 (7.597)	24.9	71.8	5.075 (7.933)	9.614 (−9.858 to 56.054)	0.42
Other primary care[c]	15.2	84.8	0.000 (0.000)	25.4	73.4	2.576 (1.978)	−2.576 (−12.413 to 0.000)	

Assessment point	Treatment group: Surgery (*n* = 171) Missing, %	Surgery (*n* = 171) Zero counts, %	Surgery (*n* = 171) Mean (SE)	PHT (*n* = 177) Missing, %	PHT (*n* = 177) Zero counts, %	PHT (*n* = 177) Mean (SE)	Surgery vs. PHT Mean difference (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Social care contacts (minutes)								
Community physiotherapy	15.8	84.2	0.000 (0.000)	25.4	74.6	0.000 (0.000)	0.000 (0.000 to 0.000)	
Home care worker	15.8	84.2	0.000 (0.000)	25.4	74.6	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other social care[d]	15.8	84.2	0.000 (0.000)	25.4	74.6	0.000 (0.000)	0.000 (0.000 to 0.000)	
Medications (item)								
Medications	15.8	56.7	19.375 (4.514)	24.9	58.2	9.609 (4.697)	9.766 (−1.582 to 39.771)	0.094
Aids and adaptations (per item/pair where appropriate)								
Crutches	17.5	69.0	0.305 (0.046)	26.6	71.8	0.046 (0.048)	0.259 (0.211 to 0.618)	< 0.001
Stick	17.5	82.5	0.000 (0.000)	26.6	72.9	0.008 (0.007)	−0.008 (−0.039 to 0.000)	
Grab rail	17.5	82.5	0.000 (0.000)	26.6	73.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Dressing aids	17.5	82.5	0.000 (0.000)	26.6	73.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other aids and adaptations[e]	17.5	81.3	0.035 (0.022)	26.6	71.8	0.031 (0.023)	0.005 (−0.087 to 0.117)	0.924

a Other inpatient admissions reported included burns and plastics, cholecystectomy, general surgery, colonoscopy, laparoscopy, ectopic pregnancy, surgical management of miscarriage, kidney infection, physiotherapy, septoplasty, varicocele embolisation, water retention, bone marrow biopsy, gastrointestinal surgery and hernia operation.
b Other outpatient attendance reported included hernia consultant; ear, nose and throat; urology; occupational health; diabetes clinic; mental health unit; and neurology.
c Other primary care consultations included acupuncture, cognitive–behavioural therapy, chiropractor, osteopathy, dentist, health-care assistant, NHS walk-in centre, massage, occupational health, psychology and psychotherapy.
d Other social care contacts included support provided by family members (e.g. parents).
e Other aids and adaptations reported included long-handle shoe horns, ankle brace, bath seat, bath sliding, bath step, thera bands, catheters (post-prostatectomy rehabilitation), moon boot, perching stool, raised toilet seat, toilet frame, trigger-operated picker, new trainers, insoles, umbrella, kneeling stool for work, new workstation chair, wedge cushion, trekking pole, toilet raised seat and barefoot shoes.

TABLE 46 Source of unit costs of primary and secondary care services (NHS and private)

Category	Currency code	Unit cost (£)	Source
Inpatients (per day of inpatient stay)			
Orthopaedics (hip/leg)	Weighted average of lower limb orthopaedic HRGs	1032.31	Reference costs (2016)[77]
Rehabilitation unit	VC36Z	357.42	
Day case	Weighted average of lower limb orthopaedic HRGs	1872.47	
Pain injection	AB19Z	691	
Burns and plastics	JB31A, JB31B, JB31C, JB32A, JB32B, JB32C, JB33A, JB33B and JB33C	966.34	
Cholecystectomy	GA10H, GA10J, GA10K, GA10L, GA10M, GA10N and GA11Z	1737.81	
General surgery	GA10H, GA10J, GA10K, GA10L, GA10M, GA10N and GA11Z	1737.81	
Colonoscopy	FZ51Z, FZ52Z and FZ53Z	793.29	
Hernia	GA10H, GA10J, GA10K, GA10L, GA10M, GA10N and GA11Z	1703.3	
Surgery general	Weighted average of upper limb orthopaedic HRGs	1872.47	
Septoplasty	CA11A	1638.88	
Varicocele embolisation	YR56Z	1177.53	
Accident and emergency	Accident and emergency, admitted	203.55	
Outpatients (per contact)			
General surgery	100	130.06	Reference costs (2016)[77]
Urology	101	105.19	
Trauma and orthopaedics	110	117.01	
Ear, nose and throat	120	96.87	
Plastics clinic	160	99.95	
Accident and emergency	180	146.86	
Pain clinic	191	139.12	
General medicine	300	309	
Diabetes	307	159.31	
Cardiology	320	127.67	
Dermatology	330	101.63	
Breast clinic	370	170.85	
Neurology	400	175.6	
Rheumatology	410	142.74	
Dentist	450	111.18	
Eye clinic	460	63.46	
Gynaecology	502	133.01	
Midwife	560	75.15	
Osteopath	650	48.33	

TABLE 46 Source of unit costs of primary and secondary care services (NHS and private) (*continued*)

Category	Currency code	Unit cost (£)	Source
Physiotherapy	650	48.33	
Chiropractor	653	42.84	
Podiatrist	653	39.2	
Mental health	710	287.57	
Blood test	DAPS05	3	
Fertility clinic	502	133.01	
Gastroscopy	FZ93A	186.75	
Hydrotherapy	650	48.33	
Occupational health	300	167.05	
Light treatment therapy	Phototherapy		
MRI	RD01A	145.14	
MRI spinal	RD01A	145.14	
Computerised tomography	RD20A	93.93	
DMSA scan	RN30A	261.28	
Bowl screening	FZ54Z	198.29	
X-ray	X-rays	30.23	
Primary and social care (cost/minute)			
Acupuncture		0.87	Community health professional (band 7) cost per hour = £52 (PSSRU 2016, section 9[52])
Chiropractor		0.87	
Physiotherapy		0.87	
Osteopathy		0.63	
Massage		0.87	
Pharmacist		0.87	
Psychology		0.87	
Counsellor		51.1	£50 per hour (PSSRU 2014, p. 51[89]) updated to 2016 prices using Hospital and Community Health Services pay and price inflation index[52]
District nurse/health visitor/midwife		0.87	Nurse (band 7) cost per hour = £52 (PSSRU 2016, section 10.1[52])
Practice nurse		0.72	Practice nurse cost per hour (with qualifications) = £43 (PSSRU 2016, section 10.2[52])
GP home visit		3.9	GP home visit lasting 11.4 minutes (PSSRU 2015, Table 10.8a[90]). Added cost of 2.18 minutes of GP time for every home visits
GP surgery		3.9	Cost per surgery consultation lasting 9.22 minutes = £36 (PSSRU 2016, Table 10.3b[52])
GP telephone		3.9	
Health-care assistant		0.4	Nurse (band 3) cost per hour = £24 (PSSRU 2016, section 10.1[52])

continued

TABLE 46 Source of unit costs of primary and secondary care services (NHS and private) (*continued*)

Category	Currency code	Unit cost (£)	Source
Adaptations: NHS supplied (per item)			
Crutches		5.05	
Stick		1.66	
Walking frame		1.61	
Grab rail		1.66	
Dressing aids		3.94	
Long-handle shoe horns		63.15	
Ankle brace		10.8	MPC code S385B-1 from supply chain catalogue[56]
Bath seat		11.13	
Bath sliding		2.58	
Bath step		10.02	
Bands from physiotherapy		19.2	NHS Foundation Trust[91]
Catheters		20.71	South & West Devon Formulary and Referral[92]
Adaptations: private purchase (per item)			
Moon boot		12.84	
Perching stool		46.18	
Raised toilet seat		7.42	
Private costs			
Physiotherapy		1.17	The Physiotherapy Centre[93]
Toilet frame		17.8	
Trigger-operated picker		12.61	amazon.co.uk[94]
New trainers		31.99	Sports Direct[95]
Insoles		9.99	Sports Direct[96]
Umbrella		34.99	Sports Direct[97]
Kneeling stool for work		49.99	amazon.co.uk[98]
New workstation chair		24.99	amazon.co.uk[99]
Wedge cushion		18.99	amazon.co.uk[100]
Trekking pole		13.99	amazon.co.uk[101]

DMSA, dimercapto succinic acid; MPC, Manufacturer Product Code.

TABLE 47 Costs associated with reported health and social care service use

Assessment point	Treatment group: Surgery (*n* = 171) Missing, %	Surgery (*n* = 171) Zero costs, %	Surgery (*n* = 171) Mean (£) (SE)	PHT (*n* = 177) Missing, %	PHT (*n* = 177) Zero costs, %	PHT (*n* = 177) Mean (£) (SE)	Surgery vs. PHT Mean difference (£) (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Baseline								
Inpatient costs								
Orthopaedics (hip/leg)	1.2	91.8	73.3 (22.89)	0.6	89.3	108.63 (22.43)	−35.33 (−162.74 to 41.51)	0.254
Orthopaedics (other)	1.2	98.8	0.00 (0.00)	0.6	98.9	10.72 (10.69)	−10.72 (−53.39 to 0.00)	
Rehabilitation unit	1.2	98.8	0.00 (0.00)	0.6	98.9	2.03 (2.03)	−2.03 (−10.12 to 0.00)	
Day case	1.2	94.7	77.56 (24.17)	0.6	97.7	31.92 (23.69)	45.64 (−25.59 to 181.82)	0.158
Pain injection	1.2	98.2	4.09 (4.05)	0.6	98.9	3.93 (3.97)	0.16 (−18.68 to 19.75)	0.936
Other inpatient stay[a]	1.2	96.5	30.41 (19.18)	0.6	96.6	45.55 (18.8)	−15.14 (−112.72 to 59.81)	0.546
Total inpatient costs	1.2	85.4	185.36 (39.95)	0.6	84.2	202.77 (39.15)	−17.41 (−210.64 to 141.44)	0.754
Outpatient costs								
Orthopaedics (hip/leg)	1.2	43.3	122.55 (10.48)	1.1	41.2	125.7 (10.3)	−3.15 (−56.32 to 49.93)	0.848
Orthopaedics (other)	1.2	90.6	10.58 (3.76)	1.1	88.7	14.08 (3.69)	−3.50 (−23.79 to 10.59)	0.534
Physiotherapy (hip/leg)	1.2	97.7	0.86 (0.89)	1.1	96.6	1.93 (0.88)	−1.08 (−5.96 to 1.91)	0.38
Physiotherapy (other)	1.2	94.7	6.95 (2.88)	1.1	94.9	7.55 (2.83)	−0.60 (−13.96 to 11.10)	0.864
Radiology	1.2	95.3	8.13 (3.48)	1.1	93.8	8.13 (3.42)	0.01 (−14.47 to 16.21)	0.918
Other outpatient[b]	1.2	88.9	26.1 (8.18)	1.7	89.3	23.38 (8.06)	2.73 (−29.10 to 42.12)	0.85
Total outpatient costs	1.2	33.3	175.17 (13.93)	1.7	29.9	181.68 (13.73)	−6.51 (−83.13 to 65.48)	0.742
Primary care costs								
GP surgery	1.2	64.3	123.18 (58.39)	1.1	58.8	35.9 (57.38)	87.28 (−12.69 to 440.65)	0.268
GP home visit	1.2	98.8	0.00 (0.00)	1.1	98.9	0.00 (0.00)	0.00 (0.00 to 0.00)	
GP telephone	1.2	90.6	3.88 (2.62)	1.1	94.4	5.01 (2.57)	−1.13 (−14.20 to 6.80)	0.842

continued

TABLE 47 Costs associated with reported health and social care service use (*continued*)

Assessment point	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
	Missing, %	Zero costs, %	Mean (£) (SE)	Missing, %	Zero costs, %	Mean (£) (SE)	Mean difference (£) (bootstrap 95% CI)	*p*-value
Practice nurse	1.2	95.9	1.75 (1.09)	1.1	94.9	0.48 (1.07)	1.26 (−1.02 to 7.51)	0.676
District nurse	1.2	98.8	0.00 (0.00)	1.1	98.3	0.10 (0.10)	−0.10 (−0.50 to 0.00)	
Community physiotherapy	1.2	96.5	1.52 (2.69)	1.1	92.1	9 (2.64)	−7.48 (−23.93 to -1.97)	0.01
Other primary care[c]	1.2	95.9	3.16 (38.18)	1.1	96.6	54.65 (37.52)	−51.49 (−264.13 to 6.74)	0.482
Total primary care costs	1.2	57.3	133.49 (71.28)	1.1	53.1	105.15 (70.05)	28.34 (−253.42 to 396.08)	0.81
Social care costs								
Community physiotherapy	1.8	98.2	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Home care worker	1.8	97.7	1.11 (1.10)	0.6	99.4	0.00 (0.00)	1.11 (0.00 to 5.70)	0.724
Other social care[d]	1.8	98.2	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total social care costs	1.8	97.7	1.11 (1.10)	0.6	99.4	0.00 (0.00)	1.11 (0.00 to 5.70)	0.724
Medications								
Medication costs	3.5	63.7	0.62 (1.5)	0.6	71.8	2.08 (1.45)	−1.47 (−9.81 to 1.68)	0.71
Aids and adaptations								
Crutches	2.3	95.3	0.18 (0.09)	0.6	97.7	0.14 (0.09)	0.04 (−0.33 to 0.43)	0.754
Stick	2.3	97.1	0.01 (0.01)	0.6	99.4	0.00 (0.00)	0.01 (0.00 to 0.05)	0.722
Grab rail	2.3	97.1	0.01 (0.01)	0.6	99.4	0.00 (0.00)	0.01 (0.00 to 0.05)	0.71
Dressing aids	2.3	97.7	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Other aids and adaptations[e]	2.3	97.7	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total aids and adaptation costs	2.3	94.2	0.2 (0.09)	0.6	97.7	0.14 (0.09)	0.06 (−0.31 to 0.47)	0.646
Total at baseline costs	4.1	12.3	502.12 (90.38)	1.7	13.6	508.53 (87.74)	−6.41 (−235.01 to 246.59)	0.88

Assessment point	Treatment group: Surgery (*n* = 171) Missing, %	Surgery (*n* = 171) Zero costs, %	Surgery (*n* = 171) Mean (£) (SE)	PHT (*n* = 177) Missing, %	PHT (*n* = 177) Zero costs, %	PHT (*n* = 177) Mean (£) (SE)	Surgery vs. PHT Mean difference (£) (bootstrap 95% CI)	Surgery vs. PHT *p*-value
6 months post randomisation								
Inpatient costs								
Orthopaedics (hip/leg)	17.0	56.7	690.63 (169.54)	22.0	71.8	175.94 (171.98)	514.69 (231.61 to 1639.05)	0.002
Orthopaedics (other)	17.0	82.5	26.57 (21.16)	22.0	77.4	13.67 (21.46)	12.90 (−62.88 to 132.78)	0.912
Rehabilitation unit	17.0	81.3	7.55 (18.19)	22.0	77.4	25.9 (18.45)	−18.35 (−118.58 to 22.59)	0.674
Day case	17.0	82.5	13.19 (16.23)	22.0	76.8	27.14 (16.46)	−13.95 (−102.90 to 50.42)	0.5
Pain injection	17.0	83.0	0.00 (0.00)	22.0	77.4	5.01 (4.42)	−5.01 (−25.30 to 0.00)	
Other inpatients[a]	17.0	81.3	44.31 (25.66)	22.0	78.0	0.00 (0.00)	44.31 (0.00 to 167.76)	0.086
Total inpatient costs	17.0	55.0	782.25 (178.9)	22.0	69.5	247.66 (181.48)	534.59 (203.05 to 1720.75)	0.008
Outpatient costs								
Orthopaedics (hip/leg)	17.5	52.0	110.37 (27.71)	22.0	65.5	72.92 (28.01)	37.45 (−69.46 to 180.88)	0.33
Orthopaedics (other)	17.5	56.1	87.75 (13.74)	22.0	47.5	107.17 (13.89)	−19.42 (−98.42 to 33.10)	0.356
Physiotherapy (hip/leg)	17.5	79.5	5.48 (3.53)	22.0	73.4	8.76 (3.57)	−3.27 (−21.63 to 8.90)	0.492
Physiotherapy (other)	17.5	80.1	6.25 (3.02)	22.0	75.1	5.32 (3.06)	0.93 (−9.77 to 15.42)	0.906
Radiology	17.5	80.7	4.12 (2.31)	22.0	77.4	2.1 (2.33)	2.01 (−7.17 to 13.08)	0.57
Other outpatients[b]	18.1	77.2	16.2 (5.72)	22.0	71.8	14.63 (5.76)	1.57 (−20.73 to 29.39)	0.862
Total outpatient costs	18.1	33.9	201.41 (28)	22.0	33.9	210.9 (28.21)	−9.49 (−161.42 to 118.18)	0.84
Primary care costs								
GP surgery	17.5	50.9	42.27 (9.84)	20.9	58.8	38.03 (9.87)	4.24 (−41.83 to 49.61)	0.732
GP home visit	17.5	81.9	0.54 (0.49)	20.9	79.1	0.00 (0.00)	0.54 (0.00 to 2.86)	0.758
GP telephone	17.5	76.0	4.99 (2.08)	20.9	75.7	3.43 (2.09)	1.56 (−7.44 to 11.70)	0.56
Practice nurse	17.5	71.9	1.76 (0.48)	20.9	75.1	0.89 (0.48)	0.87 (−0.98 to 3.30)	0.202

continued

TABLE 47 Costs associated with reported health and social care service use (*continued*)

Assessment point	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
	Missing, %	Zero costs, %	Mean (£) (SE)	Missing, %	Zero costs, %	Mean (£) (SE)	Mean difference (£) (bootstrap 95% CI)	*p*-value
District nurse	17.5	77.8	0.78 (0.35)	20.9	78.5	0.37 (0.35)	0.40 (–1.02 to 2.16)	0.39
Community physiotherapy	17.5	76.0	8.76 (2.62)	20.9	75.7	3.98 (2.63)	4.78 (–3.63 to 19.24)	0.194
Other primary care[c]	17.5	80.1	2.47 (2.52)	21.5	75.7	4.76 (2.54)	–2.30 (–15.46 to 7.01)	0.512
Total primary care costs	17.5	41.5	61.57 (11.8)	21.5	50.3	51.81 (11.88)	9.76 (–45.49 to 67.60)	0.556
Social care costs								
Community physiotherapy	17.0	81.3	2.13 (1.29)	20.9	78.5	0.81 (1.3)	1.32 (–2.65 to 8.19)	0.528
Home care worker	17.0	83.0	0.00 (0.00)	20.9	79.1	0.00 (0.00)	0.00 (0.00 to 0.00)	–
Other social care[d]	17.0	83.0	0.00 (0.00)	20.9	79.1	0.00 (0.00)	0.00 (0.00 to 0.00)	–
Total social care costs	17.0	81.3	2.13 (1.29)	20.9	78.5	0.81 (1.3)	1.32 (–2.65 to 8.19)	0.528
Medication costs								
Total medication cost	17.5	47.4	0.32 (0.14)	21.5	59.3	0.25 (0.14)	0.07 (–0.51 to 0.72)	0.788
Aids and adaptations								
Crutches	18.1	57.3	2.85 (0.28)	22.6	75.7	0.18 (0.28)	2.67 (3.02 to 5.44)	< 0.001
Stick	18.1	80.7	0.04 (0.02)	22.6	76.8	0.01 (0.02)	0.02 (–0.04 to 0.14)	0.554
Grab rail	18.1	81.3	0.02 (0.02)	22.6	77.4	0.00 (0.00)	0.02 (0.00 to 0.12)	0.764
Dressing aids	18.1	77.8	0.84 (0.34)	22.6	77.4	0.00 (0.00)	0.84 (0.32 to 2.64)	0.004
Other aids and adaptations[e]	18.1	80.1	1.39 (0.76)	22.6	77.4	0.00 (0.00)	1.39 (0.00 to 5.15)	0.114
Total cost of aids and adaptations	18.1	56.1	5.14 (0.79)	22.6	75.1	0.2 (0.8)	4.94 (4.72 to 11.63)	
Total at 6-month assessment point	20.5	16.4	875.49 (103.01)	25.4	18.1	499.33 (104.56)	376.16 (53.16 to 637.80)	0.022

Assessment point	Treatment group: Surgery ($n = 171$) Missing, %	Surgery ($n = 171$) Zero costs, %	Surgery ($n = 171$) Mean (£) (SE)	PHT ($n = 177$) Missing, %	PHT ($n = 177$) Zero costs, %	PHT ($n = 177$) Mean (£) (SE)	Surgery vs. PHT Mean difference (£) (bootstrap 95% CI)	Surgery vs. PHT *p*-value
12 months post randomisation								
Inpatient costs								
Orthopaedics (hip/leg)	14.6	69.6	753.16 (328.9)	23.7	67.8	137.95 (342.03)	615.21 (91.64 to 2626.04)	0.002
Orthopaedics (other)	14.6	85.4	0.00 (0.00)	23.7	74.6	69.87 (36.37)	−69.87 (−263.69 to 0.00)	
Rehabilitation unit	14.6	84.8	2.45 (2.5)	23.7	75.7	2.65 (2.6)	−0.20 (−12.62 to 11.17)	0.748
Day case	14.6	81.3	89.78 (25.67)	23.7	75.7	13.87 (26.7)	75.91 (13.15 to 241.63)	0.028
Pain injection	14.6	84.8	4.73 (4.82)	23.7	75.7	5.12 (5.02)	−0.39 (−23.56 to 16.26)	0.698
Other inpatients[a]	15.2	83.6	15.15 (47.75)	24.9	72.9	117.97 (49.85)	−102.82 (−412.52 to 28.94)	0.132
Total inpatient costs	15.2	62.6	871.13 (338.25)	24.9	63.3	339.07 (353.18)	532.06 (−192.26 to 2520.93)	0.192
Outpatient costs								
Orthopaedics (hip/leg)	15.8	46.2	77.19 (8.12)	23.7	65.0	33.8 (8.39)	43.39 (30.89 to 105.08)	< 0.001
Orthopaedics (other)	15.8	52.0	126.19 (16.37)	23.7	61.0	39.74 (16.9)	86.46 (66.66 to 220.12)	< 0.001
Physiotherapy (hip/leg)	15.8	80.1	14.1 (5.53)	23.7	72.9	7.16 (5.71)	6.94 (−11.20 to 38.17)	0.388
Physiotherapy (other)	15.8	81.3	5.1 (3.34)	23.7	70.1	14.14 (3.44)	−9.04 (−30.13 to 0.83)	0.072
Radiology	15.8	81.9	4.03 (2.23)	23.7	74.0	4.78 (2.3)	−0.75 (−12.10 to 8.40)	0.852
Other outpatients[b]	15.8	78.4	15.85 (8.15)	24.9	63.8	38.86 (8.48)	−23.01 (−73.33 to −0.64)	0.046
Total outpatient costs	15.8	26.3	242.46 (21.84)	24.9	39.5	134.43 (22.73)	108.03 (64.21 to 283.44)	< 0.001

continued

TABLE 47 Costs associated with reported health and social care service use (*continued*)

	Treatment group							
	Surgery ($n = 171$)			PHT ($n = 177$)			Surgery vs. PHT	
Assessment point	Missing, %	Zero costs, %	Mean (£) (SE)	Missing, %	Zero costs, %	Mean (£) (SE)	Mean difference (£) (bootstrap 95% CI)	*p*-value
Primary care costs								
GP surgery	15.2	55.0	48.61 (8.68)	24.9	49.2	44.3 (9.06)	4.31 (−29.55 to 50.04)	0.774
GP home visit	15.2	84.8	0.00 (0.00)	24.9	75.1	0.00 (0.00)	0.00 (0.00 to 0.00)	
GP telephone	15.2	78.9	4.06 (2.7)	24.9	67.8	7.13 (2.82)	−3.07 (−19.96 to 5.91)	0.482
Practice nurse	15.2	78.9	1.49 (0.55)	24.9	69.5	1.22 (0.57)	0.27 (−1.79 to 2.97)	0.73
District nurse	15.2	82.5	0.51 (1.5)	24.9	72.3	3.63 (1.57)	−3.12 (−12.71 to 0.67)	0.16
Community physiotherapy	15.2	81.3	12.78 (6.61)	24.9	71.8	4.42 (6.9)	8.36 (−8.57 to 48.77)	0.42
Other primary care[c]	15.2	84.8	0.00 (0.00)	25.4	73.4	2.24 (1.72)	−2.24 (−10.80 to 0.00)	
Total primary care costs	15.2	50.3	67.45 (12.11)	25.4	44.1	62.88 (12.69)	4.57 (−43.57 to 67.87)	0.852
Social care costs								
Community physiotherapy	15.8	84.2	0.00 (0.00)	25.4	74.6	0.00 (0.00)	0.00 (0.00 to 0.00)	
Home care worker	15.8	84.2	0.00 (0.00)	25.4	74.6	0.00 (0.00)	0.00 (0.00 to 0.00)	
Other social care[d]	15.8	84.2	0.00 (0.00)	25.4	74.6	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total social care costs	15.8	84.2	0.00 (0.00)	25.4	74.6	0.00 (0.00)	0.00 (0.00 to 0.00)	
Medications								
Total cost of medications	15.8	56.7	0.79 (0.31)	24.9	58.2	0.32 (0.33)	0.47 (−0.40 to 2.31)	0.248

Assessment point	Treatment group: Surgery (*n* = 171) Missing, %	Surgery (*n* = 171) Zero costs, %	Surgery (*n* = 171) Mean (£) (SE)	PHT (*n* = 177) Missing, %	PHT (*n* = 177) Zero costs, %	PHT (*n* = 177) Mean (£) (SE)	Surgery vs. PHT Mean difference (£) (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Aids and adaptations								
Crutches	17.5	69.0	1.54 (0.23)	26.6	71.8	0.23 (0.24)	1.31 (1.07 to 3.12)	< 0.001
Stick	17.5	82.5	0.00 (0.00)	26.6	72.9	0.01 (0.01)	−0.01 (−0.06 to 0.00)	
Grab rail	17.5	82.5	0.00 (0.00)	26.6	73.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Dressing aids	17.5	82.5	0.00 (0.00)	26.6	73.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Other aids and adaptations[e]	17.5	81.3	0.67 (0.53)	26.6	71.8	0.83 (0.55)	−0.16 (−2.75 to 2.08)	0.774
Total cost of aids and adaptations	17.5	68.4	2.21 (0.64)	26.6	70.6	1.07 (0.67)	1.14 (−1.21 to 4.69)	0.216
Total costs at 12-month assessment point	20.5	18.7	1236.26 (366.13)	29.9	22.0	560.11 (383.44)	676.15 (−59.37 to 1810.86)	0.082
Total NHS and Personal Social Services costs over 12 months of follow-up	32.7	5.3	1640.91 (148.33)	40.7	7.3	941.02 (155.23)	699.88 (274.36 to 1121.23)	< 0.001

a Other inpatient admissions reported included burns and plastics, cholecystectomy, general surgery, colonoscopy, laparoscopy, ectopic pregnancy, surgical management of miscarriage, kidney infection, physiotherapy, septoplasty, varicocele embolisation, water retention, bone marrow biopsy, gastrointestinal surgery and hernia operation.
b Other outpatient attendance reported included hernia consultant; ear, nose and throat; urology; occupational health; diabetes clinic; mental health unit; and neurology.
c Other primary care consultations included acupuncture, cognitive–behavioural therapy, chiropractor, osteopathy, dentist, health-care assistant, NHS walk-in centre, massage, occupational health, psychology and psychotherapy.
d Other social care contacts included support provided by family members (e.g. parents).
e Other aids and adaptations reported included long-handle shoe horns, ankle brace, bath seat, bath sliding, bath step, thera bands, catheters (post-prostatectomy rehabilitation), moon boot, perching stool, raised toilet seat, toilet frame, trigger-operated picker, new trainers, insoles, umbrella, kneeling stool for work, new workstation chair, wedge cushion, trekking pole, toilet raised seat and barefoot shoes.

TABLE 48 Patient self-reports of private health-care utilisation

Assessment point	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Baseline *Primary, secondary and social care*								
Outpatient physiotherapy (number attended)	1.2	98.8	0.000 (0.000)	1.1	98.3	0.023 (0.023)	−0.023 (−0.114 to 0.000)	
Primary care physiotherapy (minutes)	1.2	97.7	1.243 (0.880)	1.1	98.9	0.000 (0.000)	1.243 (0.000 to 5.051)	0.268
Social care physiotherapy (minutes)	1.8	98.2	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other social care (minutes)	1.8	97.7	0.714 (0.708)	0.6	99.4	0.000 (0.000)	0.714 (0.000 to 3.637)	0.71
Medications (number of items)	3.5	73.7	1.024 (0.323)	0.6	74.0	0.966 (0.313)	0.058 (−1.293 to 1.373)	0.934
Aids and adaptations (item/item pair)								
Crutches	2.3	97.7	0.000 (0.000)	0.6	99.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Stick	2.3	95.3	0.024 (0.011)	0.6	97.7	0.017 (0.011)	0.007 (−0.036 to 0.061)	0.65
Grab rail	2.3	97.1	0.012 (0.009)	0.6	98.9	0.006 (0.009)	0.006 (−0.020 to 0.060)	0.832
Dressing aids	2.3	95.9	0.018 (0.011)	0.6	98.9	0.011 (0.011)	0.007 (−0.041 to 0.057)	0.644
Other	2.3	94.7	0.084 (0.046)	0.6	94.4	0.068 (0.045)	0.016 (−0.140 to 0.260)	0.906
6 months post randomisation *Primary, secondary and social care*								
Outpatient physiotherapy (number attended)	17.5	82.5	0.000 (0.000)	22.0	78.0	0.000 (0.000)	0.000 (0.000 to 0.000)	
Primary care physiotherapy (minutes)	17.5	80.7	3.191 (2.083)	20.9	79.1	0.000 (0.000)	3.191 (0.000 to 12.503)	0.092
Social care physiotherapy (minutes)	17.0	83.0	0.000 (0.000)	20.9	79.1	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other social care (minutes)	17.0	83.0	0.000 (0.000)	20.9	79.1	0.000 (0.000)	0.000 (0.000 to 0.000)	
Medications (number of items)	17.5	57.3	5.603 (2.732)	21.5	60.5	0.619 (2.752)	4.984 (0.680 to 21.518)	0.008

Assessment point	Treatment group: Surgery ($n = 171$) Missing, %	Surgery ($n = 171$) Zero counts, %	Surgery ($n = 171$) Mean (SE)	PHT ($n = 177$) Missing, %	PHT ($n = 177$) Zero counts, %	PHT ($n = 177$) Mean (SE)	Surgery vs. PHT Mean difference (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Aids and adaptations (item/item pair)								
Crutches	18.1	80.7	0.029 (0.018)	22.6	77.4	0.000 (0.000)	0.029 (0.000 to 0.115)	0.256
Stick	18.1	80.7	0.014 (0.013)	22.6	76.3	0.022 (0.014)	−0.008 (−0.076 to 0.042)	0.674
Grab rail	18.1	81.9	0.000 (0.000)	22.6	77.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Dressing aids	18.1	80.7	0.014 (0.009)	22.6	77.4	0.000 (0.000)	0.014 (0.000 to 0.058)	0.266
Other	18.1	76.0	0.1 (0.044)	22.6	71.2	0.139 (0.044)	−0.039 (−0.257 to 0.122)	0.53
12 months post randomisation *Primary, secondary and social care*								
Outpatient physiotherapy (number attended)	15.8	84.2	0.000 (0.000)	23.7	76.3	0.000 (0.000)	0.000 (0.000 to 0.000)	
Primary care physiotherapy (minutes)	15.2	83.6	3.621 (4.323)	24.9	74.0	5.865 (4.514)	−2.244 (−25.070 to 13.874)	0.736
Social care physiotherapy (minutes)	15.8	83.6	0.312 (0.287)	25.4	74.6	0.000 (0.000)	0.312 (0.000 to 1.647)	0.712
Other social care (minutes)	15.8	84.2	0.000 (0.000)	25.4	74.6	0.000 (0.000)	0.000 (0.000 to 0.000)	
Medications (number of items)	16.4	71.3	0.958 (0.463)	24.9	58.8	1.256 (0.48)	−0.298 (−2.617 to 1.536)	0.618
Aids and adaptations (item/item pair)								
Crutches	17.5	82.5	0.000 (0.000)	26.6	73.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Stick	17.5	82.5	0.000 (0.000)	26.6	73.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Grab rail	17.5	81.9	0.014 (0.013)	26.6	73.4	0.000 (0.000)	0.014 (0.000 to 0.079)	0.708
Dressing aids	17.5	82.5	0.000 (0.000)	26.6	73.4	0.000 (0.000)	0.000 (0.000 to 0.000)	
Other	17.5	78.9	0.106 (0.063)	26.6	69.5	0.115 (0.065)	−0.009 (−0.244 to 0.255)	0.86

TABLE 49 Private health-care costs

Assessment point	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Baseline *Primary, secondary and social care*								
Total outpatient physiotherapy	1.2	98.8	0.00 (0.00)	1.1	98.3	1.60 (1.59)	−1.60 (−8.00 to 0.00)	
Total primary care costs	1.2	97.7	1.45 (1.03)	1.1	98.9	0.00 (0.00)	1.45 (0.00 to 5.91)	0.268
Total social care costs	1.8	98.2	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total cost of medications	3.5	73.7	1.08 (0.19)	0.6	74.0	1.03 (0.19)	0.05 (−0.83 to 0.97)	0.858
Aids and adaptations								
Crutches	2.3	97.7	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Stick	2.3	95.3	1.88 (1.08)	0.6	97.7	0.44 (1.05)	1.44 (−0.95 to 7.99)	0.396
Grab rail	2.3	97.1	0.16 (0.11)	0.6	98.9	0.02 (0.11)	0.13 (−0.08 to 0.83)	0.71
Dressing aids	2.3	95.9	0.16 (0.08)	0.6	98.9	0.06 (0.08)	0.10 (−0.18 to 0.53)	0.392
Other	2.9	94.7	1.37 (6.36)	0.6	94.4	9.82 (6.18)	−8.45 (−43.72 to 3.68)	0.386
Total cost of aids and adaptations	2.9	91.2	3.57 (6.46)	0.6	92.1	10.34 (6.27)	−6.77 (−41.43 to 8.17)	0.62
Total costs at baseline	4.7	70.2	10.89 (7.11)	1.1	69.5	14.95 (6.86)	−4.06 (−25.06 to 11.16)	0.76
6 months post randomisation *Primary, secondary and social care*								
Total outpatient physiotherapy	17.5	82.5	0.00 (0.00)	22.0	78.0	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total primary care costs	17.5	80.7	3.73 (2.44)	20.9	79.1	0.00 (0.00)	3.73 (0.00 to 14.63)	0.092
Total social care costs	17.0	83.0	0.00 (0.00)	20.9	79.1	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total cost of medications	17.5	57.3	1.12 (0.22)	21.5	60.5	1.23 (0.22)	−0.11 (−1.13 to 0.84)	0.716

Assessment point	Treatment group: Surgery (*n* = 171) Missing, %	Surgery (*n* = 171) Zero counts, %	Surgery (*n* = 171) Mean (SE)	PHT (*n* = 177) Missing, %	PHT (*n* = 177) Zero counts, %	PHT (*n* = 177) Mean (SE)	Surgery vs. PHT Mean difference (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Aids and adaptations								
Crutches	18.1	80.7	1.46 (1.29)	22.6	77.4	0.00 (0.00)	1.46 (0.00 to 7.14)	0.256
Stick	18.1	80.7	0.21 (0.3)	22.6	76.3	0.55 (0.31)	−0.33 (−2.07 to 0.55)	0.456
Grab rail	18.1	81.9	0.00 (0.00)	22.6	77.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Dressing aids	18.1	80.7	0.21 (0.14)	22.6	77.4	0.00 (0.00)	0.21 (0.00 to 0.92)	0.266
Other	18.1	76.0	8.05 (4.61)	22.6	71.2	5.31 (4.66)	2.75 (−11.93 to 28.37)	0.778
Total cost of aids and adaptations	18.1	73.7	9.94 (4.73)	22.6	70.6	5.85 (4.78)	4.08 (−10.29 to 31.00)	0.608
Total private medical costs at 6 months	19.9	50.3	19.73 (5.11)	24.9	55.4	4.86 (5.19)	14.87 (3.32 to 31.31)	0.006
12 months post randomisation *Primary, secondary and social care*								
Total outpatient physiotherapy	15.8	84.2	0.00 (0.00)	23.7	76.3	0.00 (0.00)	0.00 (0.00 to 0.00)	
Total primary care costs	15.2	83.6	4.24 (5.06)	24.9	74.0	6.86 (5.28)	−2.63 (−29.33 to 16.23)	0.736
Total social care costs	15.8	83.6	0.37 (0.34)	25.4	74.6	0.00 (0.00)	0.37 (0.00 to 1.93)	0.712
Total cost of medications	16.4	71.3	0.67 (0.2)	24.9	58.8	0.92 (0.2)	−0.24 (−1.28 to 0.49)	0.384
Aids and adaptations								
Crutches	17.5	82.5	0.00 (0.00)	26.6	73.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Stick	17.5	82.5	0.00 (0.00)	26.6	73.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Grab rail	17.5	81.9	0.57 (0.52)	26.6	73.4	0.00 (0.00)	0.57 (0.00 to 3.16)	0.708
Dressing aids	17.5	82.5	0.00 (0.00)	26.6	73.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Other	17.5	78.9	2.01 (4.19)	26.6	69.5	9.45 (4.37)	−7.43 (−34.91 to 3.79)	0.202
Total cost of aids and adaptations	17.5	78.4	2.58 (4.21)	26.6	69.5	9.45 (4.39)	−6.86 (−34.36 to 4.63)	0.246
Total costs at 12-month point	20.5	64.3	11.43 (7.13)	27.7	53.1	19.56 (7.35)	−8.13 (−29.57 to 9.55)	0.43
Total costs over 12 months of follow-up	32.2	36.3	32.67 (10.24)	37.9	38.4	27.44 (10.51)	5.23 (−23.55 to 32.41)	0.704

TABLE 50 Additional costs

	Treatment group							
	Surgery ($n = 172$)			PHT ($n = 177$)			Surgery vs. PHT	
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Baseline								
Lost earnings	1.2	91.8	151.7 (78.85)	0.6	92.7	66.86 (77.27)	84.83 (−124.67 to 512.25)	0.502
Help with housework	1.2	98.2	1.78 (2.81)	0.6	98.3	4.55 (2.75)	−2.77 (−17.57 to 6.34)	0.468
Child care	1.2	98.8	0.00 (0.00)	0.6	98.9	8.24 (8.22)	−8.24 (−42.24 to 0.00)	
Special equipment	1.2	98.2	0.3 (2.2)	0.6	97.7	4.26 (2.16)	−3.97 (−16.88 to 0.45)	0.082
Other	1.2	91.2	10.38 (9.44)	0.6	88.1	27.58 (9.25)	−17.20 (−72.85 to 7.68)	0.154
Total additional costs at baseline	1.2	84.8	164.15 (80.28)	0.6	81.9	111.49 (78.66)	52.66 (−189.36 to 470.01)	0.748
6 months post randomisation								
Lost earnings	15.8	73.7	309.51 (78.71)	18.6	76.8	8.37 (78.71)	301.15 (162.19 to 842.50)	< 0.001
Help with housework	15.8	83.0	3.51 (5.92)	18.6	80.2	10.28 (5.92)	−6.77 (−40.58 to 11.43)	0.432
Child care	15.8	83.6	3.47 (2.57)	18.6	80.2	1.39 (2.57)	2.08 (−4.83 to 17.86)	0.794
Special equipment	15.8	83.0	1.25 (0.65)	18.6	80.8	0.23 (0.65)	1.02 (−0.67 to 4.84)	0.282
Other	15.8	70.8	141.78 (87.43)	18.6	70.6	12.49 (87.43)	129.29 (−6.41 to 625.59)	0.154
Total additional costs at 6 months	15.8	61.4	459.53 (116.58)	18.6	66.7	32.76 (116.58)	426.77 (226.04 to 1199.80)	< 0.001
12 months post randomisation								
Lost earnings	13.5	77.2	637.36 (262.83)	22.0	74.6	132.1 (272.19)	505.26 (−40.90 to 2221.03)	0.074
Help with housework	13.5	86.0	0.61 (0.57)	22.0	78.0	0.00 (0.00)	0.61 (0.00 to 3.14)	0.694
Child care	13.5	86.0	0.81 (0.75)	22.0	78.0	0.00 (0.00)	0.81 (0.00 to 4.24)	0.77
Special equipment	13.5	86.5	0.00 (0.00)	22.0	78.0	0.00 (0.00)	0.00 (0.00 to 0.00)	
Other	13.5	81.3	11.22 (3.77)	22.0	73.4	4.41 (3.91)	6.80 (−3.36 to 28.08)	0.158
Total additional costs at 12 months	13.5	71.9	650 (262.76)	22.0	70.6	136.51 (272.11)	513.49 (−31.90 to 2244.99)	0.064
Total additional costs over 12 months of follow-up	22.8	50.9	1143.2 (325.37)	29.9	52.5	184.81 (335.7)	958.39 (219.74 to 2001.32)	0.004

TABLE 51 Benefit payments received during follow-up

	Treatment group							
	Surgery ($n = 171$)			PHT ($n = 177$)			Surgery vs. PHT	
Assessment point	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Baseline								
Attendance Allowance	1.2	98.8	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Income Support	1.2	97.7	1.05 (0.76)	0.6	99.4	0.00 (0.00)	1.05 (0.00 to 4.36)	0.266
Housing Benefit	1.2	96.5	1.82 (1.63)	0.6	98.3	2.36 (1.6)	−0.54 (−8.92 to 4.97)	0.87
Carer's Allowance	1.2	98.8	0.00 (0.00)	0.6	98.9	0.34 (0.34)	−0.34 (−1.73 to 0.00)	
Child Tax Credit	1.2	94.2	4.37 (1.6)	0.6	96.6	2.16 (1.57)	2.21 (−3.41 to 10.76)	0.348
DLA, mobility	1.2	98.2	0.12 (0.15)	0.6	98.9	0.17 (0.15)	−0.05 (−0.84 to 0.58)	0.712
DLA, caring	1.2	98.8	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Pension Credit	1.2	98.8	0.00 (0.00)	0.6	99.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Council Tax Reduction	1.2	98.2	0.01 (0.01)	0.6	99.4	0.00 (0.00)	0.01 (0.00 to 0.03)	0.744
Employment and Support Allowance	1.2	94.2	3.11 (0.89)	0.6	98.9	0.41 (0.87)	2.70 (0.79 to 8.70)	0.014
Personal Independence Payment	1.2	98.2	5.77 (5.74)	0.6	99.4	0.00 (0.00)	5.77 (0.00 to 29.26)	0.77
Statutory Sick Pay	1.2	98.2	0.52 (4.17)	0.6	98.3	6.18 (4.09)	−5.66 (−28.33 to 1.65)	0.35
Other payments[a]	2.3	95.9	0.65 (0.39)	0.6	98.9	0.28 (0.38)	0.37 (−0.92 to 2.35)	0.498
Total benefit payments at baseline	2.3	87.1	17.62 (6.54)	0.6	93.2	11.9 (6.37)	5.72 (−20.89 to 36.78)	0.512
6 months post randomisation								
Attendance Allowance	15.8	84.2	0.00 (0.00)	18.6	81.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Income Support	15.8	83.6	0.69 (0.64)	18.6	81.4	0.00 (0.00)	0.69 (0.00 to 3.53)	0.71
Housing Benefit	15.8	81.3	2.56 (1.02)	18.6	80.8	0.76 (1.02)	1.80 (−1.33 to 7.60)	0.234

continued

TABLE 51 Benefit payments received during follow-up (*continued*)

Assessment point	Treatment group: Surgery ($n = 171$) Missing, %	Surgery ($n = 171$) Zero counts, %	Surgery ($n = 171$) Mean (SE)	PHT ($n = 177$) Missing, %	PHT ($n = 177$) Zero counts, %	PHT ($n = 177$) Mean (SE)	Surgery vs. PHT Mean difference (bootstrap 95% CI)	Surgery vs. PHT *p*-value
Carer's Allowance	15.8	84.2	0.00 (0.00)	18.6	81.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Child Tax Credit	15.8	80.1	4.03 (1.99)	18.6	78.5	3.37 (1.99)	0.66 (–9.07 to 9.53)	0.78
DLA, mobility	15.8	84.2	0.00 (0.00)	18.6	80.8	0.15 (0.13)	–0.15 (–0.77 to 0.00)	
DLA, caring	15.8	83.6	0.22 (0.31)	18.6	80.8	0.38 (0.31)	–0.16 (–1.85 to 0.98)	0.694
Pension Credit	15.8	84.2	0.00 (0.00)	18.6	81.4	0.00 (0.00)	0.00 (0.00 to 0.00)	
Council Tax Reduction	15.8	82.5	0.47 (0.25)	18.6	81.4	0.00 (0.00)	0.47 (0.00 to 1.68)	0.088
Employment and Support Allowance	15.8	79.5	5.00 (1.88)	18.6	81.4	0.00 (0.00)	5.00 (2.60 to 15.14)	0.002
Personal Independence Payment	16.4	82.5	1.86 (1.22)	19.2	80.8	0.00 (0.00)	1.86 (0.00 to 7.38)	0.282
Statutory Sick Pay	16.4	77.2	29.43 (13.69)	19.2	80.2	1.57 (13.69)	27.86 (2.77 to 116.29)	0.018
Other payments[a]	15.8	83.0	1.42 (1.01)	19.2	80.2	0.84 (1.01)	0.58 (–2.99 to 5.35)	0.744
Total benefit payments at the 6-month assessment point	17.0	68.4	46.12 (14.27)	20.3	75.1	7.21 (14.32)	38.91 (14.21 to 135.48)	0.006
12 months post randomisation								
Attendance Allowance	13.5	86.0	0.07 (0.06)	22.0	78.0	0.00 (0.00)	0.07 (0.00 to 0.34)	0.818
Income Support	13.5	86.5	0.00 (0.00)	22.0	78.0	0.00 (0.00)	0.00 (0.00 to 0.00)	
Housing Benefit	13.5	84.8	0.87 (0.51)	22.0	77.4	0.36 (0.53)	0.51 (–1.22 to 3.35)	0.532
Carer's Allowance	13.5	86.5	0.00 (0.00)	22.0	78.0	0.00 (0.00)	0.00 (0.00 to 0.00)	
Child Tax Credit	13.5	84.8	1.1 (1.44)	22.0	76.8	2.46 (1.49)	–1.36 (–10.24 to 2.94)	0.574
DLA, mobility	13.5	85.4	0.75 (0.52)	22.0	78.0	0.00 (0.00)	0.75 (0.00 to 3.28)	0.276
DLA, caring	13.5	84.8	1.14 (0.74)	22.0	78.0	0.00 (0.00)	1.14 (0.00 to 5.08)	0.112

Assessment point	Treatment group						Surgery vs. PHT	
	Surgery ($n = 171$)			PHT ($n = 177$)				
	Missing, %	Zero counts, %	Mean (SE)	Missing, %	Zero counts, %	Mean (SE)	Mean difference (bootstrap 95% CI)	*p*-value
Pension Credit	14.0	85.4	2.04 (1.89)	22.0	78.0	0.00 (0.00)	2.04 (0.00 to 10.23)	0.788
Council Tax Reduction	13.5	85.4	0.14 (0.35)	22.0	77.4	0.51 (0.36)	−0.37 (−2.41 to 0.51)	0.622
Employment and Support Allowance	13.5	84.2	2.72 (1.1)	22.0	76.8	1.06 (1.14)	1.67 (−1.84 to 8.20)	0.282
Personal Independence Payment	14.0	84.2	2.20 (1.47)	22.0	78.0	0.00 (0.00)	2.20 (0.00 to 9.57)	0.102
Statutory Sick Pay	13.5	82.5	5.1 (2.07)	22.6	76.3	0.65 (2.16)	4.45 (0.10 to 18.65)	0.048
Other payments[a]	14.0	84.8	0.98 (0.6)	22.0	77.4	0.51 (0.62)	0.47 (−1.73 to 3.66)	0.698
Total benefit payments at the 12-month assessment point	14.6	74.9	17.31 (4.3)	22.6	74.6	5.58 (4.44)	11.72 (1.49 to 38.39)	0.038
Total benefit payments over 12 months of follow-up	25.1	57.3	57.93 (16.34)	31.6	62.7	12.94 (16.8)	44.99 (10.88 to 97.42)	< 0.001

DLA, Disability Living Allowance.

a Other benefit payments reported include Industrial Injuries Disablement Benefit, Jobseeker's Allowance, Student Loan/Maintenance Grant and Working Tax Credit.

TABLE 52 Summary of EQ-5D-3L responses from the feasibility study sample ($n = 97$)

Assessment point	Treatment group, *n* (%)[a]		*p*-value[b]
	Surgery ($N = 46$)	PHT ($N = 51$)	
Baseline			
Mobility			
No problems	19 (40.4)	21 (41.2)	1
Some problems	25 (53.2)	30 (58.8)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	3 (6.4)	0 (0.0)	
Self-care			
No problems	35 (74.5)	47 (92.2)	0.138
Some problems	9 (19.1)	4 (7.8)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	3 (6.4)	0 (0.0)	
Usual activities			
No problems	13 (27.7)	14 (27.5)	1
Some problems	27 (57.4)	33 (64.7)	
Severe problems	4 (8.5)	4 (7.8)	
Missing	3 (6.4)	0 (0.0)	
Pain and discomfort			
No problems	2 (4.3)	3 (5.9)	1
Some problems	31 (66.0)	39 (76.5)	
Severe problems	11 (23.4)	9 (17.6)	
Missing	3 (6.4)	0 (0.0)	
Anxiety and depression			
No problems	22 (46.8)	30 (58.8)	0.444
Some problems	18 (38.3)	16 (31.4)	
Severe problems	4 (8.5)	4 (7.8)	
Missing	3 (6.4)	1 (2.0)	
6 months post randomisation			
Mobility			
No problems	23 (48.9)	22 (43.1)	0.662
Some problems	19 (40.4)	24 (47.1)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	5 (10.6)	5 (9.8)	
Self-care			
No problems	37 (78.7)	42 (82.4)	0.885
Some problems	5 (10.6)	4 (7.8)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	5 (10.6)	5 (9.8)	

TABLE 52 Summary of EQ-5D-3L responses from the feasibility study sample ($n = 97$) (*continued*)

Assessment point	Treatment group, *n* (%)[a]		*p*-value[b]
	Surgery ($N = 46$)	PHT ($N = 51$)	
Usual activities			
No problems	13 (27.7)	18 (35.3)	0.563
Some problems	25 (53.2)	24 (47.1)	
Severe problems	4 (8.5)	4 (7.8)	
Missing	5 (10.6)	5 (9.8)	
Pain and discomfort			
No problems	6 (12.8)	7 (13.7)	1
Some problems	28 (59.6)	33 (64.7)	
Severe problems	7 (14.9)	6 (11.8)	
Missing	6 (12.8)	5 (9.8)	
Anxiety and depression			
No problems	21 (44.7)	28 (54.9)	0.418
Some problems	18 (38.3)	14 (27.5)	
Severe problems	3 (6.4)	4 (7.8)	
Missing	5 (10.6)	5 (9.8)	
12 months post randomisation *Mobility*			
No problems	21 (44.7)	18 (35.3)	0.651
Some problems	18 (38.3)	21 (41.2)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	8 (17.0)	12 (23.5)	
Self-care			
No problems	31 (66.0)	34 (66.7)	0.543
Some problems	8 (17.0)	5 (9.8)	
Severe problems	0 (0.0)	0 (0.0)	
Missing	8 (17.0)	12 (23.5)	
Usual activities			
No problems	16 (34.0)	16 (31.4)	1
Some problems	21 (44.7)	22 (43.1)	
Severe problems	2 (4.3)	1 (2.0)	
Missing	8 (17.0)	12 (23.5)	
Pain and discomfort			
No problems	9 (19.1)	8 (15.7)	1
Some problems	24 (51.1)	26 (51.0)	
Severe problems	6 (12.8)	5 (9.8)	
Missing	8 (17.0)	12 (23.5)	

continued

TABLE 52 Summary of EQ-5D-3L responses from the feasibility study sample ($n = 97$) (*continued*)

Assessment point	Treatment group, *n* (%)[a]		*p*-value[b]
	Surgery ($N = 46$)	PHT ($N = 51$)	
Anxiety and depression			
No problems	25 (53.2)	26 (51.0)	1
Some problems	9 (19.1)	13 (25.5)	
Severe problems	5 (10.6)	0 (0.0)	
Missing	8 (17.0)	12 (23.5)	

a These patients were recruited into the feasibility study sample in which the EQ-5D data were collected using the three-level version of the questionnaire.
b *p*-values were generated from chi-squared tests for differences in suboptimal levels of function for each dimension in which responses indicating no functional impairment were categorised as optimal and responses indicating any functional impairment were categorised as suboptimal.

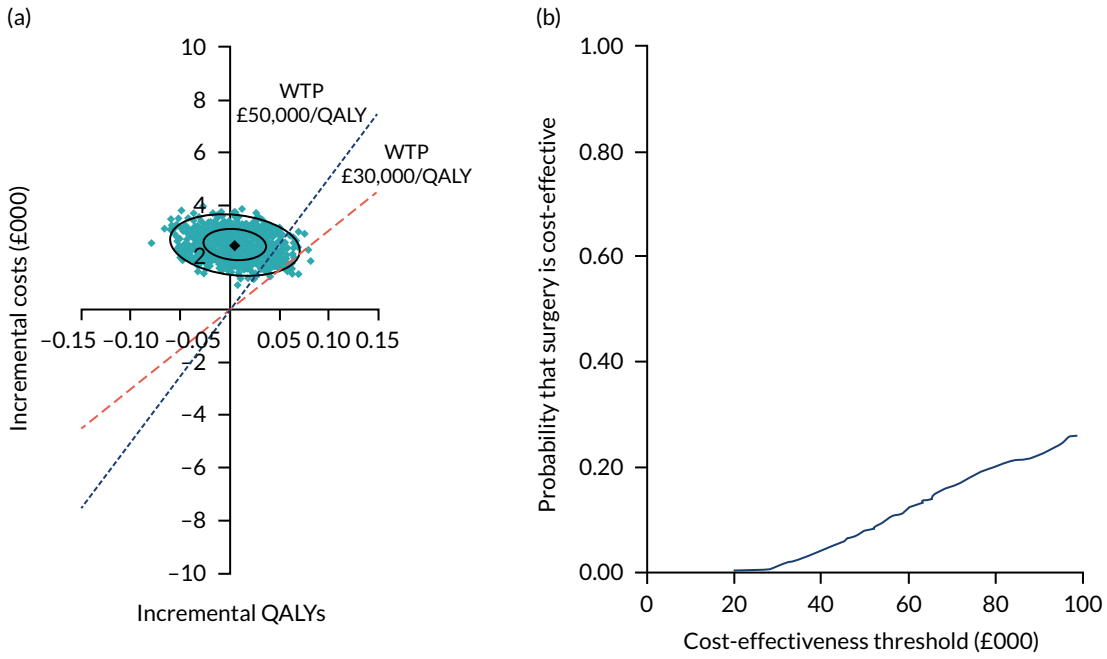

FIGURE 15 Sensitivity analysis 1: unadjusted analysis based on multiple imputed data sets under the missing-at-random assumption. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

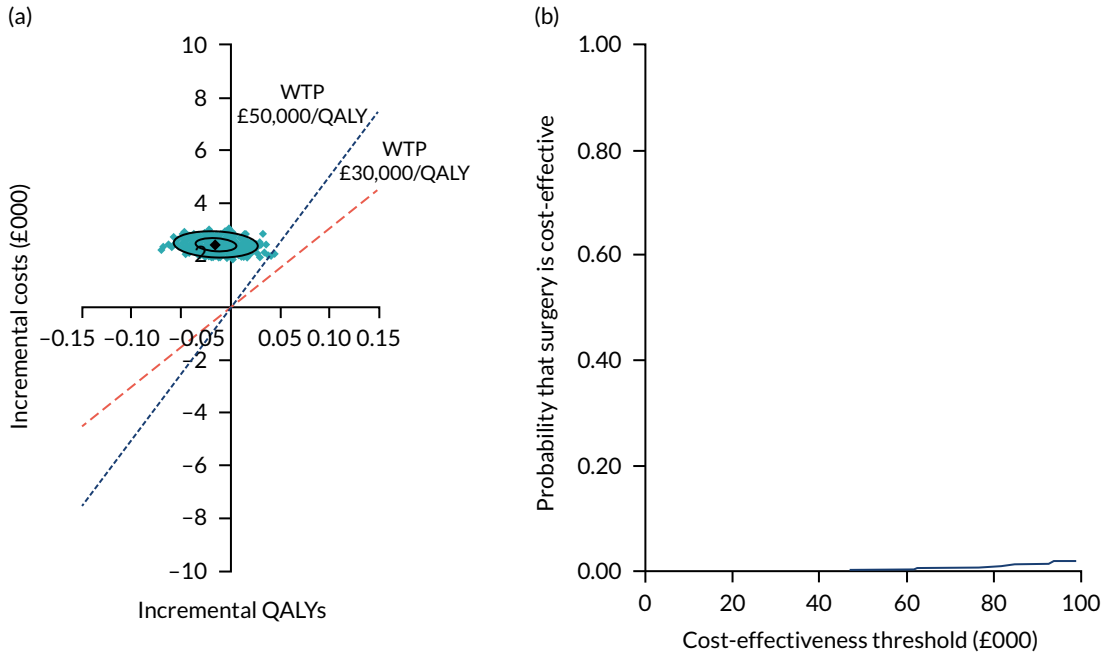

FIGURE 16 Sensitivity analysis 2: complete-case (adjusted) analysis. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

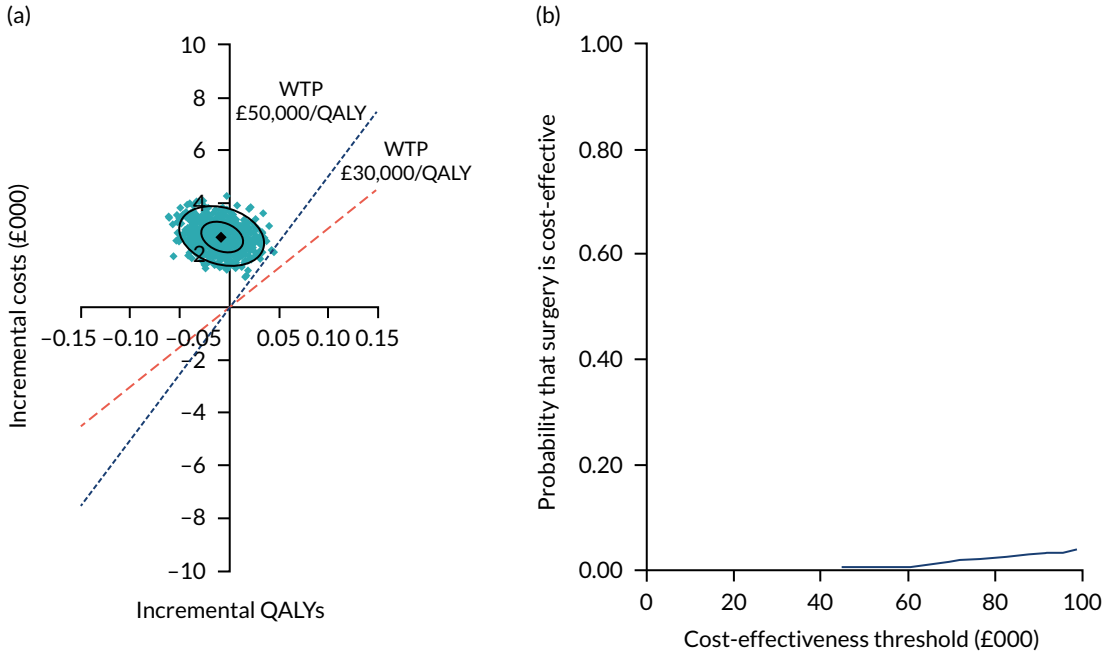

FIGURE 17 Sensitivity analysis 3: per-protocol (adjusted) analysis based on imputed data. Patients who crossed over from PHT to surgery were included in the surgery group; those who did not receive the surgery or PHT were excluded. (a) Incremental costs; and (b) probability that surgery is cost-effectiveness'. WTP, willingness to pay.

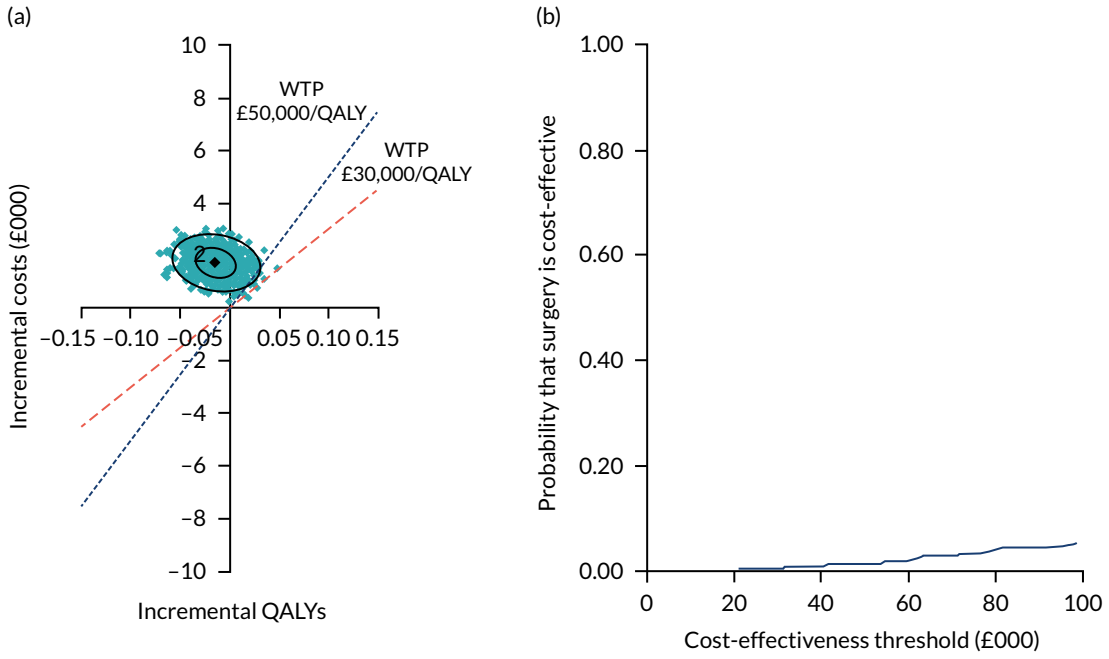

FIGURE 18 Sensitivity analysis 4: adjusted analysis based on imputed data with the cost of surgery changed from £3045 to £2680 based on HRG code HT15Z (Minor Hip Procedures for Trauma, elective long stay). (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

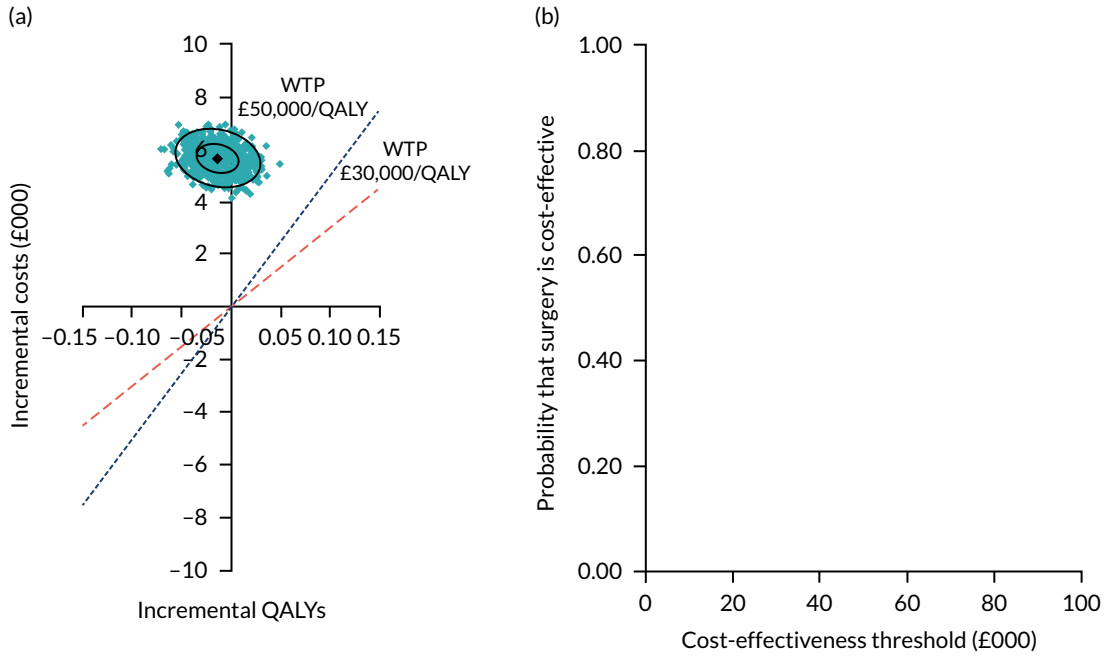

FIGURE 19 Sensitivity analysis 5: adjusted analysis based on imputed data with the cost of surgery changed from £3045 to £5811 based on HRG code HT12A (Very Major Hip Procedures for Trauma with CC Score 12 +, elective long stay). (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

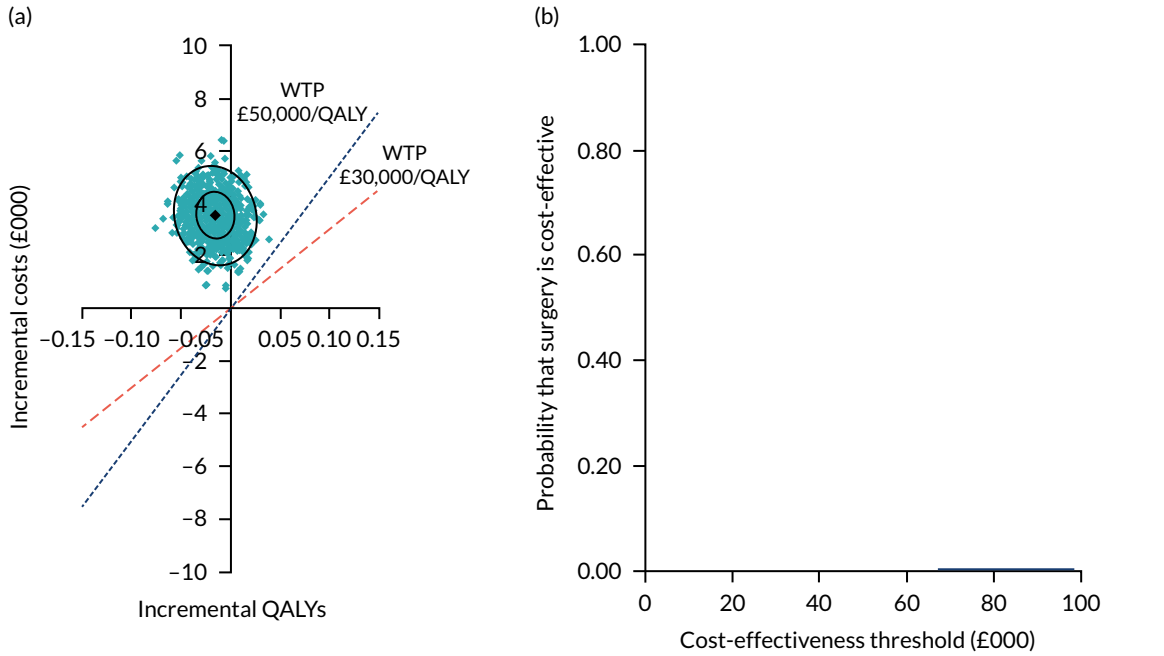

FIGURE 20 Sensitivity analysis 6: adjusted analysis based on imputed data. Economic costs calculated from a societal perspective (including NHS/Personal Social Services costs, private health costs and non-health-related costs, such as lost income due to illness). (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

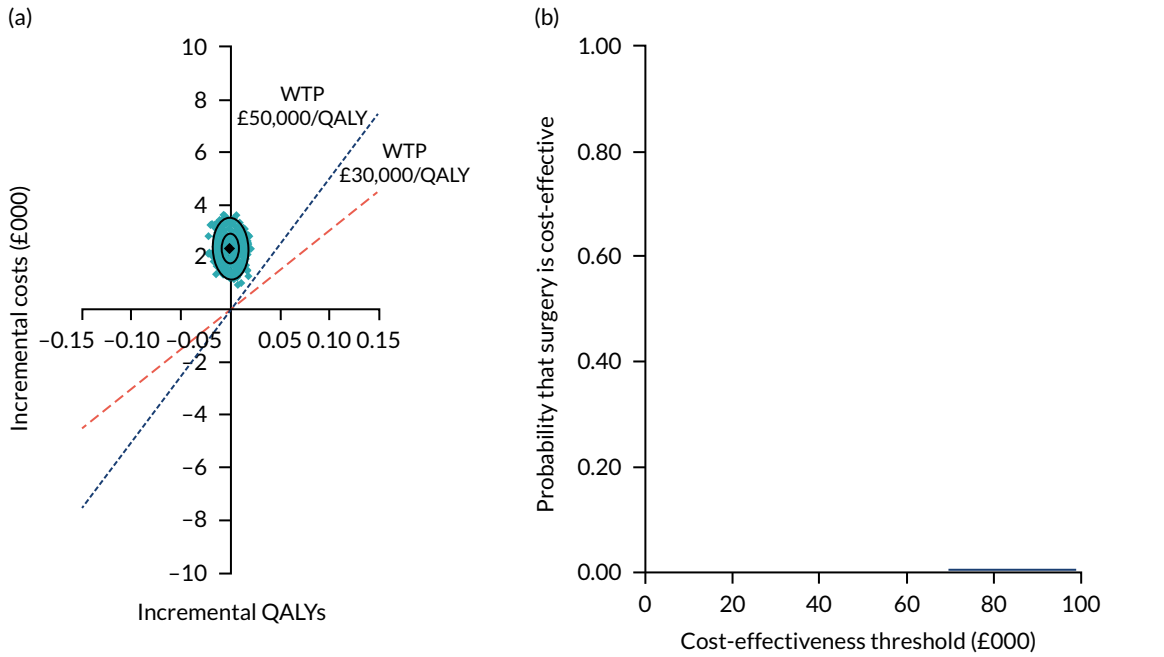

FIGURE 21 Sensitivity analysis 8: adjusted analysis based on imputed data. Adjusted analysis based on imputed data sets using QALYs generated from SF-6D (via SF-12). (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

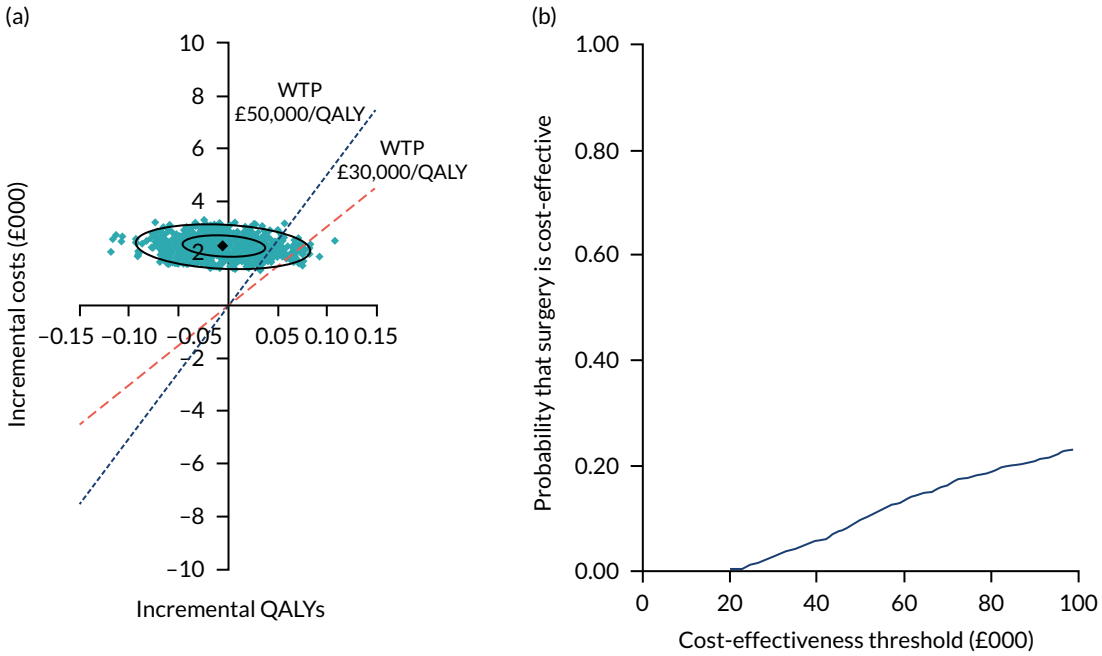

FIGURE 22 Subgroup of patients recruited into the feasibility study (unadjusted analysis based on multiple imputed data sets). (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

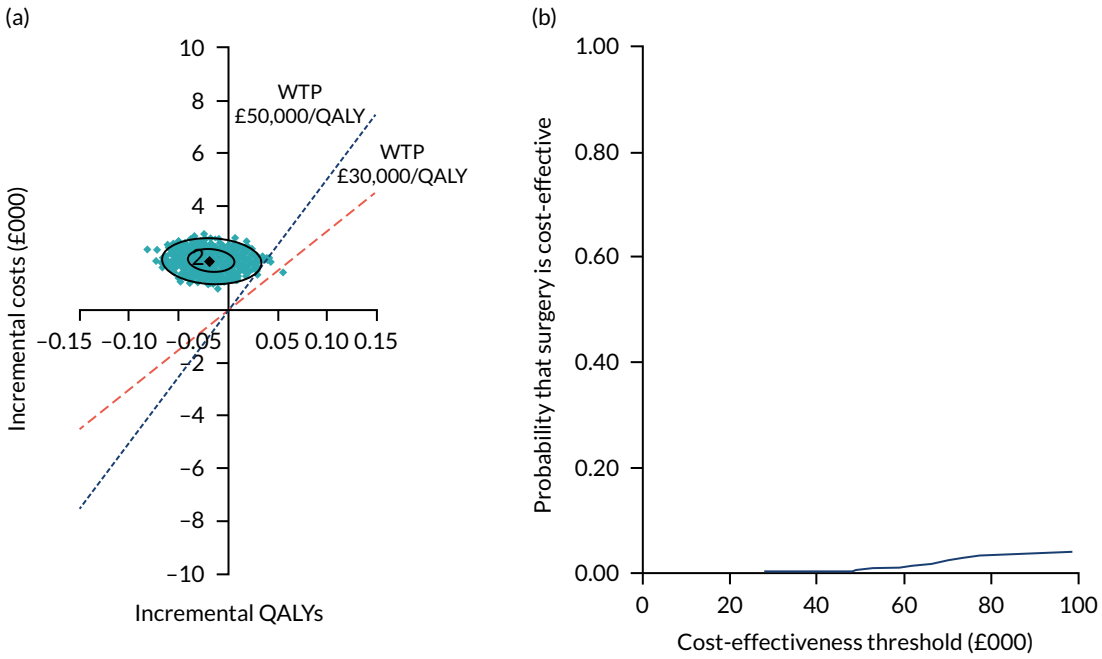

FIGURE 23 Subgroup of patients recruited into the main study sample (unadjusted analysis based on multiple imputed data sets) with QALYs generated using the interim EQ-5D-5L to EQ-5D-3L UK crosswalk tariffs. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

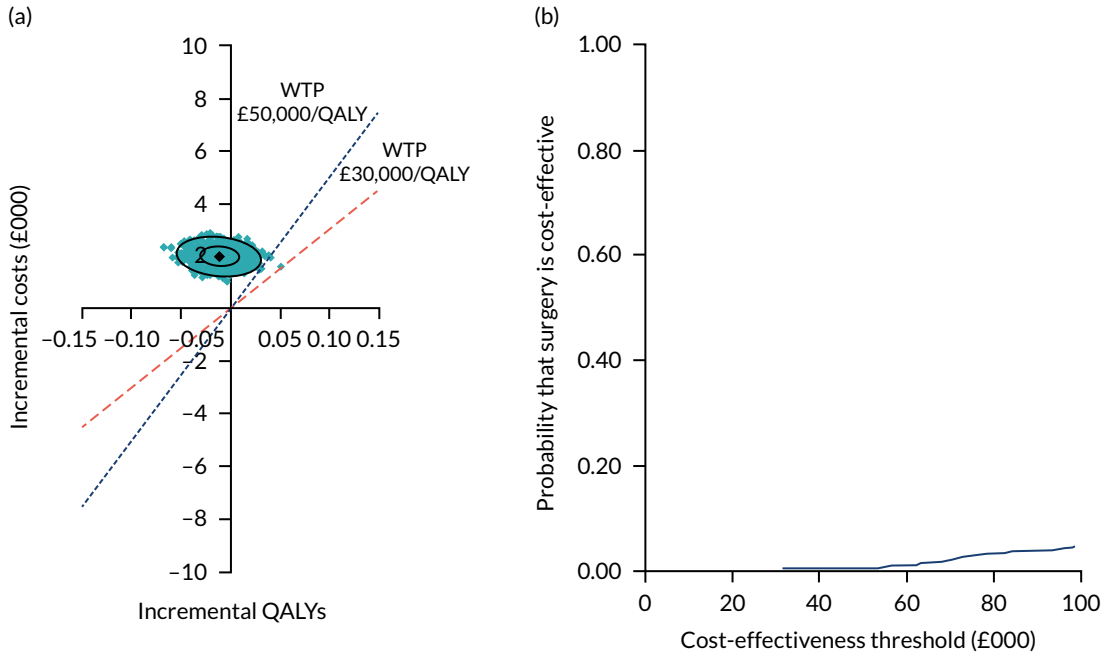

FIGURE 24 Subgroup of patients recruited into the main study sample (unadjusted analysis based on multiple imputed data sets) with QALYs generated using the new UK EQ-5D-5L tariffs derived by Devlin *et al.*[64] (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

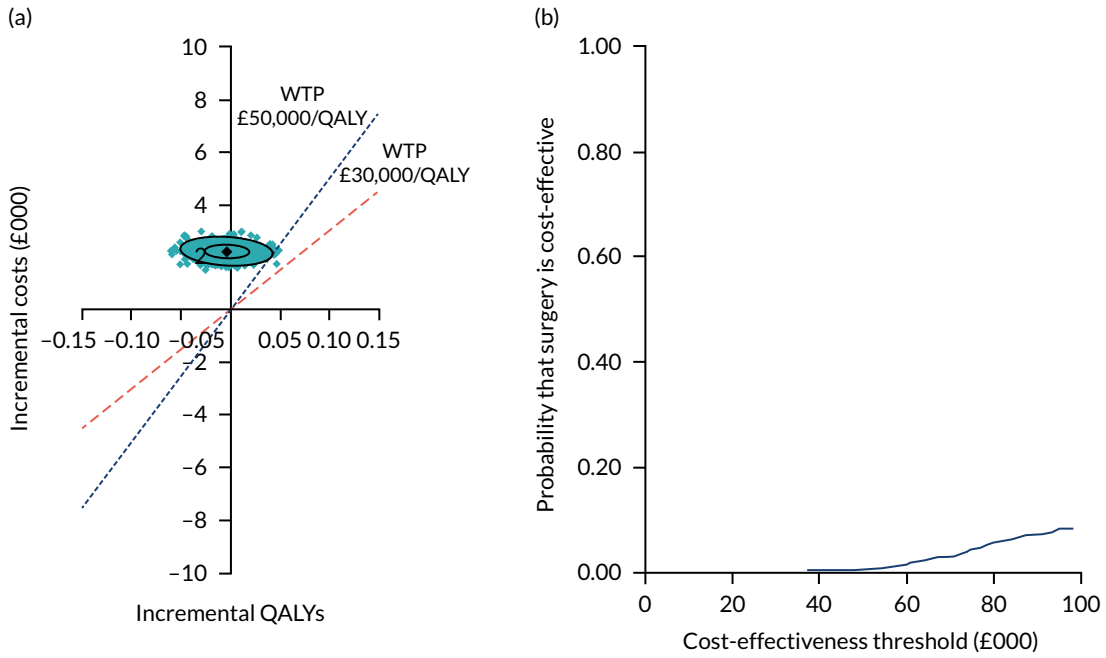

FIGURE 25 Subgroup of patients with cam FAI syndrome. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

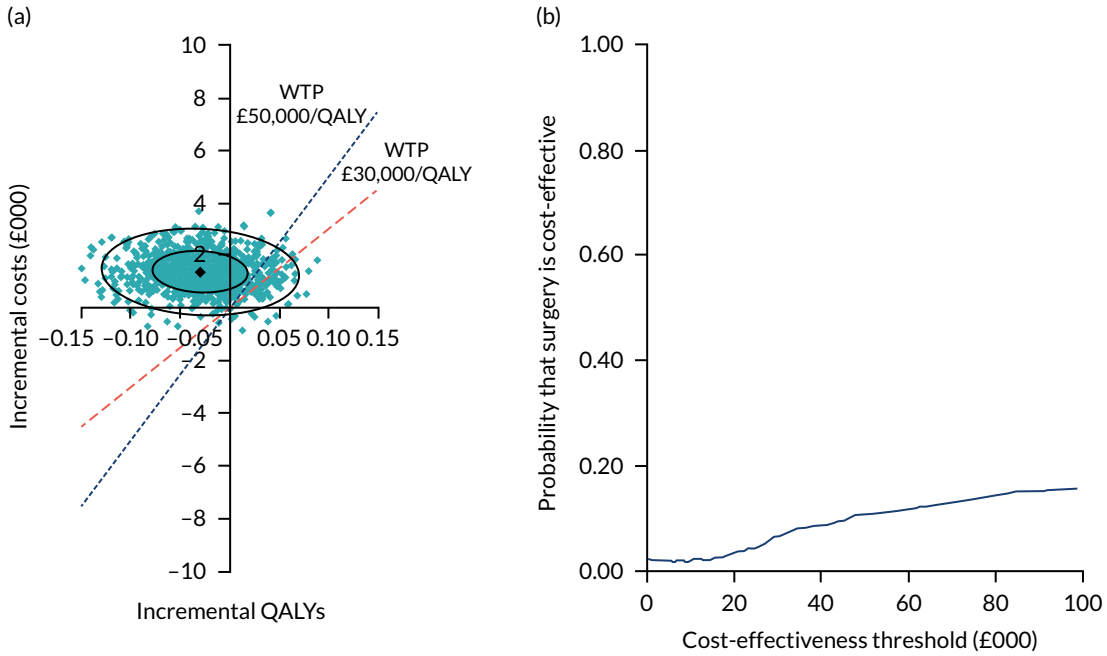

FIGURE 26 Subgroup of patients with mixed or pincer (non-cam) FAI syndrome. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

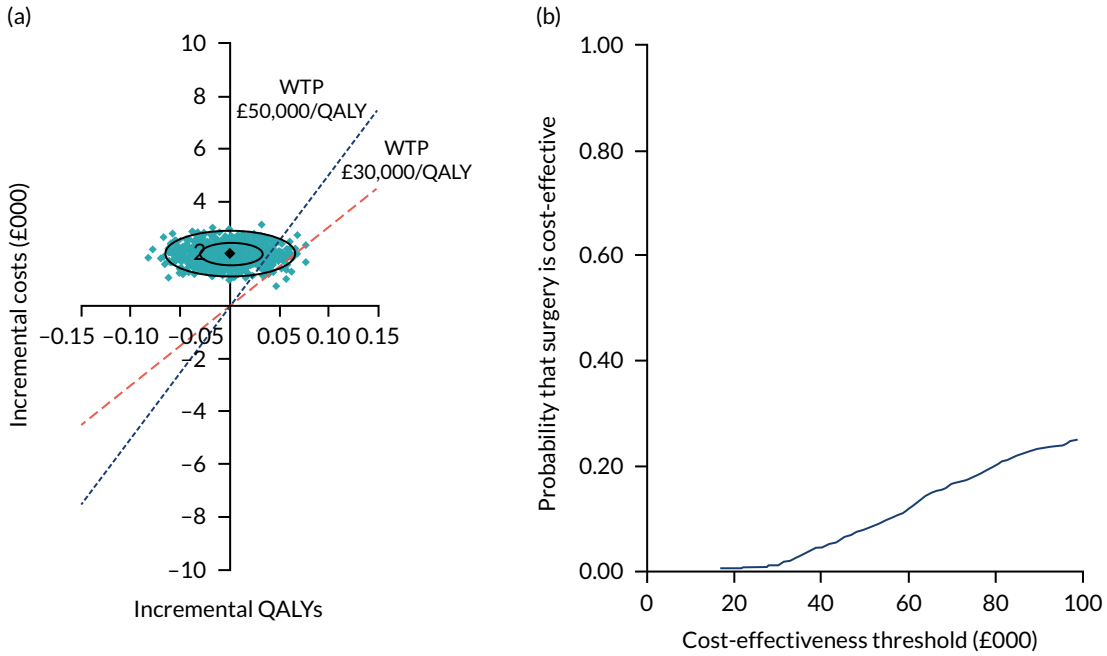

FIGURE 27 Restricted analysis to women. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

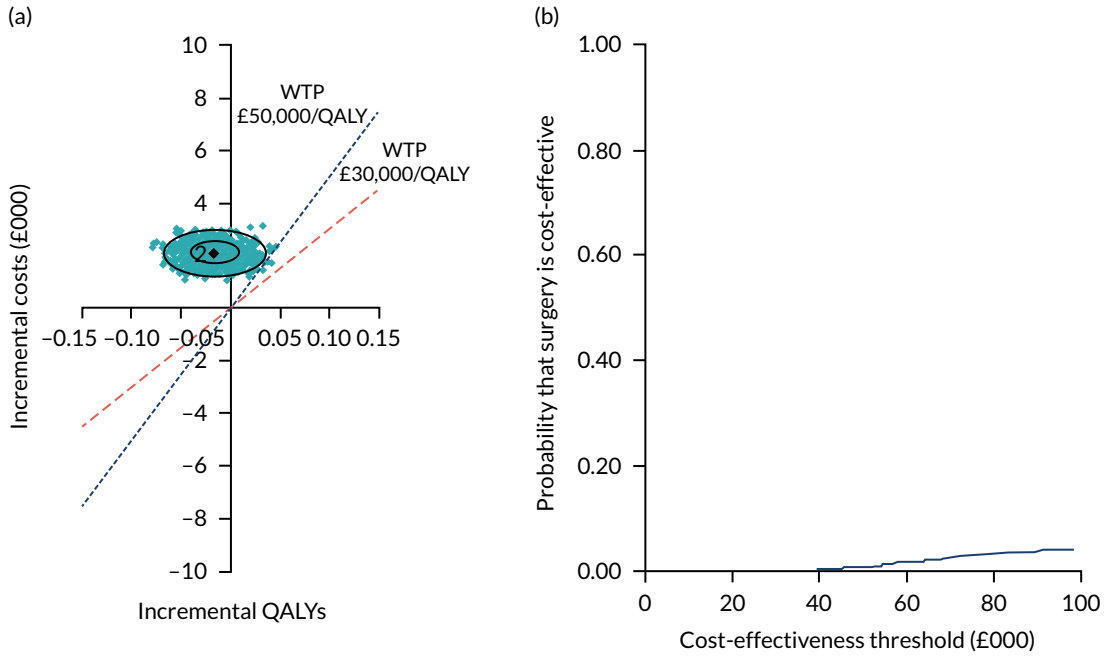

FIGURE 28 Restricted analysis to men. (a) Incremental costs; and (b) probability that surgery is cost-effective. WTP, willingness to pay.

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