Arthroscopic Hip Surgery compared with Physiotherapy and Activity Modification for the Treatment of Symptomatic Femoroacetabular Impingement: A Multi-Centre Randomised Controlled Trial

Palmer AJR[1], Ayyar Gupta V[1], Fernquest S[1], Rombach I[2], Dutton SJ[2], Mansour R[3], Wood S[3], Khanduja V[4], Pollard TCB[5], McCaskie AW[6], Barker KL[1], Andrade AJMD[5], Carr AJ[1], Beard DJ[1], Glyn-Jones S[1]

+ FAIT Study Group

1. Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS), University of Oxford, UK

2. Centre for Statistics in Medicine, NDORMS, University of Oxford, UK

3. Oxford University Hospitals NHS Foundation Trust, Oxford, UK

4. Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

5. Royal Berkshire NHS Foundation Trust, Reading, UK

6. Division of Trauma and Orthopaedic Surgery, University of Cambridge, UK

FAIT Study Group:

Sion Glyn-Jones (Oxford University Hospitals NHS Foundation Trust), Tony Andrade, Tom Pollard (Royal Berkshire NHS Foundation Trust), Chris Paliobeis (Wye Valley NHS Trust), Vikas Khanduja (Cambridge University Hospitals NHS Foundation Trust), Adekoyejo Odutola (Weston Area Health NHS Trust), David Hollinghurst, Mike Rigby, Adam Brooks (Great Western Hospitals NHS Foundation Trust), Jon Conroy (Harrogate and District NHS Foundation Trust).

Corresponding Author:

Mr Antony Palmer

NIHR Academic Clinical Lecturer in Trauma and Orthopaedics
Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS)
University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

E-mail: antony.palmer@ndorms.ox.ac.uk
Twitter: @AJRPalmer
ORCID: 0000-0003-4616-7482

Mr Antony Palmer (Corresponding Author)
NIHR Academic Clinical Lecturer in Trauma and Orthopaedics, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Dr Vandana Ayyar Gupta
Trial Manager, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Dr Scott Fernquest
DPhil Student and Clinical Research Fellow, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Dr Ines Rombach
Medical Statistician, Centre for Statistics in Medicine, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Ms Susan Dutton
Lead Medical Statistician, Centre for Statistics in Medicine, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Dr Ramy Mansour
Consultant Musculoskeletal Radiologist, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust, Windmill Road, Oxford, OX3 7LD, UK

Mr Simon Wood
Senior Sports Physiotherapist, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust, Windmill Road, Oxford, OX3 7LD, UK

Mr Vikas Khanduja
Consultant Orthopaedic Surgeon, Addenbrookes Hospital, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ, UK

Mr Tom Pollard
Consultant Orthopaedic Surgeon, Royal Berkshire Hospital, Royal Berkshire NHS Foundation Trust, Craven Road, Reading RG1 5AN, UK

Prof Andrew McCaskie
Professor of Orthopaedic Surgery and Head of Department of Surgery, University of Cambridge, Hills Road, Cambridge, CB2 0QQ, UK

Prof Karen Barker
Professor of Physiotherapy, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Mr Tony Andrade
Consultant Orthopaedic Surgeon, Royal Berkshire Hospital, Royal Berkshire NHS Foundation Trust, Craven Road, Reading RG1 5AN, UK

Prof Andrew Carr
Nuffield Professor of Orthopaedic Surgery and Head of Department, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Prof David Beard
Professor of Musculoskeletal Sciences and Co-Director of Royal College of Surgeons Surgical Intervention Trials Unit, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Prof Sion Glyn-Jones
Professor of Orthopaedic Surgery, NDORMS, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK

Structured Abstract:

Objective: Compare arthroscopic hip surgery with physiotherapy and activity modification for improving patient reported outcome measures in patients with symptomatic femoroacetabular impingement (FAI).

Design: Two-group parallel, assessor-blinded, pragmatic randomised controlled study.

Setting: Secondary and tertiary care centres across seven NHS England sites.

Participants: 222 participants aged 18 to 60 years with symptomatic FAI confirmed clinically and radiologically were randomised (1:1) to receive arthroscopic hip surgery (n = 112) or physiotherapy and activity modification (n = 110). Exclusion criteria included previous surgery, completion of a physiotherapy programme targeting FAI within the preceding 12 months, established osteoarthritis (Kellgren-Lawrence ≥2), and hip dysplasia (centre-edge angle <20 degrees).

Intervention: Participants in the physiotherapy group received a goal-based programme tailored to individual patient needs with emphasis on improving core stability and movement control. Up to eight physiotherapy sessions were delivered over five months. Participants in the arthroscopic hip surgery group received surgery to excise the bone that impinged during hip movements, followed by routine post-operative care.

Main Outcome Measures: The primary outcome measure was the Hip Outcome Score Activities of Daily Living (HOS ADL) at eight months post randomisation with a minimum clinically importance difference between groups of nine points. Secondary outcome measures included additional patient reported outcome measures and clinical assessment.

Results: At eight months post-randomisation, data was available for 100 patients in the arthroscopic hip surgery group (89%) and 88 patients in the physiotherapy and activity modification group (80%). Mean HOS ADL was 78.4 (95% CI 74.4 to 82.3) for patients randomised to arthroscopic hip surgery and 69.2 (95% CI 65.2 to 73.3) for patients randomised to physiotherapy and activity modification. Adjusting for baseline HOS ADL, age, gender, and study site, mean HOS ADL was 10.0 points higher in the arthroscopic

hip surgery group compared with the physiotherapy and activity modification group (95% CI 6.4 to 13.6, p<0.001)). No serious adverse events were reported in either group.

Conclusions: Patients with symptomatic FAI referred to secondary or tertiary care achieve superior outcomes with arthroscopic hip surgery compared with non-operative measures.

Trial Registration: ClinicalTrials.gov identifier: NCT01893034.

Feasibility Study:

https://www.ncbi.nlm.nih.gov/pubmed/23610700

Protocol:

https://www.ncbi.nlm.nih.gov/pubmed/25431439

Ethics Approval:

The trial protocol was approved by Health Research Authority, National Research Ethics Services Committee South Central – Berkshire (REC reference: 13/SC/0154) and local research and development departments at each participating site.

What This Paper Adds:

What is already known on this subject:

- Femoroacetabular Impingement (FAI) describes pathological abutment of the femoral neck against the acetabular rim due to morphological abnormalities of the hip. The condition can cause pain (FAI syndrome) and is thought to be responsible for half of all hip osteoarthritis.

- The treatment of FAI remains controversial. Physiotherapy and arthroscopic surgery both demonstrate the ability to improve symptoms arising from this condition. It remains uncertain whether one treatment is superior to the other.

- Despite the absence of evidence to support the use of arthroscopic hip surgery over non-operative measures, there has been a rapid increase in the number of arthroscopic hip procedures performed each year in the UK and abroad. There is also significant regional variation in practice.

What this study adds:

- This study suggests that arthroscopic hip surgery is superior to physiotherapy and activity modification at improving patient reported outcome measures in patients referred to secondary or tertiary care with FAI syndrome.

- Not all patients benefit from surgery and the decision to operate must follow a detailed discussion between the patient and surgeon with specialist expertise in arthroscopic hip surgery.

- The results inform management decisions made by patients, clinicians, and policymakers. Further research is required to identify which patients are most likely to benefit from intervention, whether treatment is cost-effective, and if arthroscopic surgery remains superior in the long-term.

Introduction:

Femoroacetabular Impingement (FAI) is a hip condition where adverse morphology predisposes to premature joint degeneration(1, 2). This adverse morphology is classified as 'cam', 'pincer', or 'mixed'. Cam morphology describes a loss of sphericity of the femoral head, pincer morphology describes an acetabulum with excessive coverage of the femoral head, whereas mixed describes a combination of the two deformities (Figure 1). These hip shapes can cause the femoral neck to impact against the acetabular rim during a functional range of movement with resultant damage to the labrum (which is attached to the rim), delamination of the adjacent acetabular cartilage and over time, secondary osteoarthritis(1, 3).

The prevalence of FAI morphology is high and is observed in approximately one fifth of the general population(4). Less than 25% of these individuals develop pain(5) (FAI syndrome) or osteoarthritis(1), although up to one half of all hip osteoarthritis may develop secondary to FAI(2). Identifying individuals at greatest risk of developing joint pathology secondary to FAI remains a challenge.

Physiotherapy and activity modification represents the principal treatment for symptomatic FAI, however, arthroscopic surgery is increasingly adopted to reshape the hip and address damage to the labrum and cartilage (Figure 2). The primary treatment goal is to improve pain and function, but interventions that modify contact between the femoral neck and acetabular rim may subsequently reduce cartilage and joint damage, the risk of osteoarthritis, and need for future hip arthroplasty(6).

Arthroscopic hip surgery has been shown to be safe(7) but evidence of efficacy is limited. Two randomised controlled trials have been performed comparing physiotherapy rehabilitation with arthroscopy for improving symptoms: One concluded that there was no difference between treatments(8), and the other concluded arthroscopic surgery was superior to best conservative care. Despite the limited evidence, arthroscopic hip surgery has become an established treatment with over 50,000 arthroscopic hip procedures estimated to take place in the United States of America annually(9). The number of procedures performed annually in England between 2002 and 2013 increased by

727%(10). There is significant regional variation in the number of procedures performed that may reflect surgeon preferences or local commissioning of services(10).

The aim of the Femoroacetabular Impingement Trial (FAIT) is to compare arthroscopic hip surgery with physiotherapy and activity modification in patients referred to secondary or tertiary care with symptomatic FAI(11). In this manuscript, we report the primary end-point of patient-reported outcomes at eight months post-randomisation. Cost-effectiveness and osteoarthritis development will be evaluated at three-year follow-up. Study design was based on a prior feasibility study that demonstrated surgeons and patients both have equipoise with respect to physiotherapy and activity modification versus arthroscopic hip surgery(12).

Methods:

The study was performed as per the published protocol(11).

Study Design:

FAIT is a two-group parallel assessor-blinded pragmatic randomised controlled study with 1:1 allocation.

Participants:

Eligible participants were aged 18 to 60 years and referred to secondary or tertiary care with symptomatic FAI confirmed clinically and with imaging (radiography and magnetic resonance imaging). No quantitative imaging measurements were used as inclusion criteria for this study due to the absence of agreed diagnostic thresholds and to improve generalisability of study findings(13). Instead, surgeons made a qualitative assessment of hip morphology to diagnose FAI. Participants were excluded if they had completed a programme of physiotherapy targeting FAI within the preceding 12 months or received previous surgery to their symptomatic hip. Additional exclusion criteria were established osteoarthritis (Kellgren-Lawrence ≥2) or hip dysplasia (centre-edge angle <20 degrees on anteroposterior pelvis radiograph).

Recruiting Centres:

Participants were recruited by Consultant Orthopaedic Surgeons from seven NHS sites across England: Oxford University Hospitals NHS Foundation Trust, Royal Berkshire NHS Foundation Trust, Harrogate and District NHS Foundation Trust, Cambridge University Hospital NHS Foundation Trust, Wye Valley NHS Trust, Great Western Hospital NHS Foundation Trust, and Weston Area Health NHS Trust. Study participation required that sites were specialist centres that perform a high volume of arthroscopic hip procedures and could deliver the goal-based physiotherapy programme.

Randomisation and masking:

Randomisation was performed by a research nurse at each site using an automated computer-generated telephone randomisation system provided by OCTRU (Oxford Clinical Trials Research Unit).

Randomisation for the first 12 participants (10% of original sample size) was based on a simple random list and subsequent participants were randomised using a minimisation algorithm. This algorithm included a random element (80%) and aimed to generate balanced treatment allocations by age (< 40 or ≥ 40 years), gender, baseline Activities of Daily Living subscale of the Hip Outcome Score (HOS ADL) (<65% or ≥65%), and study site(11).

Masking of patients and clinicians delivering the intervention was not possible. However, clinicians performing follow-up clinical assessments (hip range of movement, strength tests and impingement tests) were blinded to the treatment group. Participants were asked not to disclose their treatment and were requested to wear shorts to cover any scars. Data entry was performed by staff members independent of the study team.

Interventions (full details in published protocol)[12]:

Physiotherapy and Activity Modification (subsequently referred to as 'Physiotherapy'): There is no agreed standardised physiotherapy regime for FAI and a goal-based programme was developed for this trial based on the consensus opinion of the study team and existing literature(14). Treatment standardisation was achieved by disseminating the study protocol and providing training sessions for participating physiotherapists. Physiotherapy compliance and attainment of goals within the prescribed treatment themes was recorded by the treating therapist. Treatment was delivered by a Specialist Physiotherapist (Band 6) or Advanced Physiotherapy Practitioner (Band 7/8) (Table S1). The programme was tailored to individual patient needs and their desired level of function with an emphasis on muscle strengthening to improve core stability and movement control. Participants were encouraged to avoid impingement positions (extremes of hip flexion, abduction, internal rotation). Up to eight sessions were provided over a five-month period to reflect what is feasible in current NHS practice.

Arthroscopic Surgery: Participating surgeons met prior to trial recruitment to ensure standardisation of technique for the study by consensus agreement. Femoral and acetabular bone seen to impinge intra-operatively was excised with a burr (osteochondroplasty) to eliminate impingement on dynamic hip flexion and internal rotation. Labral tears were repaired if possible, or otherwise debrided. Articular

cartilage lesions were debrided to a stable base and in areas of full thickness cartilage loss, microfracture of the subchondral bone was performed. Participants received post-operative physiotherapy, provided as routine care in the NHS, that focused on maintaining range of movement and a graduated return to activity.

Outcomes:

The primary outcome measure was the HOS ADL measured eight months post randomisation. The HOS ADL is a validated patient-reported outcome measure (PROM) for patients undergoing arthroscopic hip procedures[15]. The HOS ADL ranges from 0 to 100 with higher values indicating better outcomes.

Additional PROMs were collected as secondary outcome measures to evaluate symptoms: HOS Sport subscale[15], Non-Arthritic Hip Score (NAHS)[16], Copenhagen Hip And Groin Outcome Score (HAGOS)[17], Oxford Hip Score (OHS)[18], and International Hip Outcome Tool (iHOT-33)[19]. Quality of life, nature and location of pain, and psychological factors were evaluated using EQ-5D-3L[20], PainDETECT[21], and Hospital Anxiety and Depression Score (HADS)[22] respectively. Clinical assessment to examine hip range of movements, strength and impingement tests were carried out at baseline and follow up visits. At baseline, patients were also asked to complete an 'expectation' HOS ADL score to indicate the symptoms they expect to experience after treatment is complete.

Imaging measurements were performed using custom software by academic orthopaedic clinicians (AJRP and SF). Osteoarthritis was evaluated as the Kellgren-Lawrence Grade[23]. Dysplasia and pincer morphology were quantified using the centre edge angle on a standing anteroposterior radiograph. Cam morphology was measured as the maximal cartilage alpha angle at the 12 o'clock, 1 o'clock, 2 o'clock, and 3 o'clock position on MRI radial slices[24]. All Intraclass Correlation Coefficients for intra-observer and inter-observer reproducibility values exceeded 0.90 (Figure S1).

Participants will be followed-up for three years to evaluate the development of osteoarthritis in this cohort. Additional outcomes for the long-term analysis include compositional MRI (T2 mapping), serum

and urinary biomarkers of osteoarthritis, and health economic data(11). These outcomes are not reported in this manuscript.

Study Assessments:

The primary and secondary outcome measures were collected at baseline and eight months after randomisation, equating to approximately six months after intervention when taking into account the waiting times for treatment. This time-point was chosen as i) a clinically meaningful difference of nine points in the ADL HOS is detectable six months after arthroscopic hip surgery(15, 25) ii) our feasibility study demonstrated that 94% patients were willing to pursue a treatment of six months, but no longer, without improvement in their symptoms(12). Postal PROM questionnaires were also included at five months post randomisation to capture short-term fluctuations in symptoms.

If treatment commenced more than 12 weeks post randomisation, follow-up assessments were performed six months post intervention rather than eight months post randomisation to ensure the schedule remained aligned with routine clinical care. PROMs were collected at eight months post randomisation (primary outcome measure) and six months post intervention in this group.

Sample Size:

Sample size was based on the primary outcome measure, HOS ADL at eight months post randomisation, and was calculated using a minimum clinically important difference between groups of nine points(15). Standard deviation was estimated as 14 points, however, summaries presented at a planned interim data monitoring meeting demonstrated that the standard deviation was 18 points. A revised calculation (significance level 5%, power 90%, loss to follow-up 20%) gave a sample size of 214 (107 participants in each group). The sample size increase from 120 to 214 participants was approved by the data monitoring committee (DMC).

Statistical Analysis:

The statistical analysis plan was finalised before unblinding the data to study investigators. Statistical testing was performed at the two-sided 5% significance level and conducted using STATA 14.2 (StataCorp LLC, College Station, TX, USA). Analysis of the primary endpoint and all secondary endpoints was as per modified intention to treat (mITT) including patients with available outcome data based on their randomised treatment allocation, regardless of compliance. Linear regression analysis was used to compare the HOS ADL outcomes at eight months post randomisation between the treatment groups, adjusting for the minimisation factors gender, age, baseline HOS ADL, and site. Results were presented as treatment effects with 95% confidence intervals and p-values.

In addition to HOS ADL evaluation within the cohort, it was also assessed within the individual and expressed as the proportion of patients achieving: i) An increase in HOS ADL greater than 9 points (minimum detectable change and a clinically important change within an individual)(15) ii) 'Expectation' HOS ADL (score patients expect to achieve after treatment measured at baseline) iii) Patient Acceptable Symptomatic State (PASS) (outcome HOS ADL greater than 87 points)(26) within the mITT population eight months post randomisation.

Supporting analyses of the primary endpoint included a multi-level mixed-effects model with repeated measures of HOS ADL adjusting for baseline HOS ADL, gender, age, time from randomisation, and study site (Supporting Analysis A). The primary analysis was then repeated with: i) additional adjustment for HADS, and imaging measures of osteoarthritis (radiographic Kellgren-Lawrence grade) and hip morphology (maximum cartilage alpha angle on MRI, centre-edge angle on anteroposterior pelvis radiograph) (Supporting Analysis B). ii) the per protocol population (PP) excluding participants with major deviations from the trial protocol (Supporting Analysis C). iii) six months post intervention outcomes (Supporting Analysis D). Primary analysis was also repeated with the baseline 'expectation' HOS ADL as a covariate. Participants with available baseline and outcome data were included in these analyses.

The potential impact of missing data on trial conclusions was considered using multiple imputation (missing at random data) and sensitivity analysis (missing not at random data). Multiple imputation by chained equations was performed using the 'mi impute chained' command in Stata. A linear regression

model was used to impute missing outcomes for the HOS ADL at eight months post randomisation. Variables in the imputation model included all covariates in the analysis model (baseline HOS (continuous), age (continuous) and gender). In addition, other variables that were thought to be predictive of the outcome were included (lateral centre edge angle, maximum alpha angle, Kellgren-Lawrence grade, and baseline HADS scores). Imputations were run separately by treatment arm and based on a predictive mean matching approach, choosing at random one of the five HOS ADL values with the closest predicted scores. Missing data in the covariates that were included in the multiple imputation model were imputed simultaneously (multiple imputation by chained equation approach). Sensitivity analysis was performed using the 'rctmiss' command in Stata and scenarios were considered where participants with missing data in each arm were assumed to have outcomes that were up to nine points worse than when missing at random (Figure S2).

Secondary PROMs were analysed using a multilevel mixed-effects model, with repeated measures of the relevant PROM (collected at 5 and 8 months) nested within participants. The models used data from participants with available baseline and at least one follow-up assessment, adjusting for baseline PROM, gender, age, study site, and time from randomisation.

Pre-defined sub-group exploration was performed for the following participant groups: osteoarthritis grade (Kellgren-Lawrence 0 versus 1), gender, age (continuous variable), baseline HOS ADL category (continuous variable), and FAI type (pincer/cam/mixed). Treatment effects by binary subgroup were illustrated with forest plots, showing point estimates, confidence intervals and heterogeneity p-values (estimates obtained from interaction models including only the relevant subgroup and randomised treatment as covariates). The differential treatment effect for age and baseline HOS ADL (as continuous variables) was further explored by adding an interaction term for treatment*age and treatment*baseline HOS ADL into the primary analysis model. Linear and non-linear effects (squared and cubic terms) for age and baseline HOS ADL were explored..

Details on clinical examination, including range of movement and signs of impingement were summarised descriptively for each follow-up time points. The trial is registered at ClinicalTrials.gov: NCT01893034.

Patient Involvement:

A feasibility study included patient questionnaires to determine outcomes they felt were most important, treatment preferences, acceptable study design, and anticipated recruitment numbers(12). Study design was then based on these findings. A patient representative provided guidance throughout the study including an evaluation of the burden of intervention and assessments. Study results will be disseminated through publication, presentation at scientific meetings, and at patient and public engagement events coordinated by our institution. The results will also be disseminated using social media platforms.

Results:

495 patients were screened across seven orthopaedic centres between 24 May 2013 and 30 September 2016, of whom 350 (71%) met the study eligibility criteria (Figure 3). 222 (63%) of the 350 eligible patients elected to participate and were randomised to arthroscopic surgery or physiotherapy (45% of all patients screened). The principal reason for declining participation was a treatment preference for surgery 58 (45%) or physiotherapy 33 (26%). Of the 222 patients enrolled in the trial, 112 were allocated to receive arthroscopic surgery and 110 were allocated to receive physiotherapy. Baseline demographic and clinical characteristics were well balanced across treatment groups (Table 1). Mean age was 36 years (SD 9.7) and there was a higher proportion of females (66%) than males (34%). The primary pathology was isolated cam morphology FAI (94%) and at baseline the mean HOS ADL subscale was 65.9 (SD 18.7).

Table 1: Baseline Characteristics

	Physiotherapy (n = 110)	Arthroscopic Surgery (n = 112)	Total (n=222)
Left Right	51 (46.4%) 59 (53.6%)	45 (40.2%) 67 (59.8%)	96 (43.2%) 126 (56.8%)
Male Female	37 (33.6%) 73 (66.4%)	38 (33.9%) 74 (66.1%)	75 (33.8%) 147 (66.2%)
Age^	36.0 (SD 9.9) Range 18, 60 n=110	36.4 (SD 9.6) Range 18, 59 n=112	36.2 (SD 9.7) Range 18, 60
Height (cm)^	171.9 (SD 9.2) Range 154, 193 n=107	170.5 (SD 10.4) Range 151, 211 n=111	171.2 (SD 9.8) Range 151, 211
Weight (kg)^	78.6 (SD 14.6) Range 53, 117 n=108	76.1 (SD 18.7) Range 42, 143 n=109	77.3 (SD 16.8) Range 42, 143
BMI^	26.6 (SD 4.8) Range 18, 41 n=106	25.9 (SD 4.8) Range 17, 42 n=109	26.2 (SD 4.8) Range 17, 42

	Physiotherapy	Arthroscopic Surgery	Total
Baseline HOS ADL	65.7 (SD 18.9) Range 12, 99 n=110	66.1 (SD 18.5) Range 28, 99 n=112	65.9 (SD 18.7) Range 12, 99

	Physiotherapy	Arthroscopic Surgery	Total
Cam Pincer Mixed	104 (94.5%) 0 (0.0%) 6 (5.5%)	104 (92.9%) 1 (0.9%) 7 (6.3%)	208 (93.7%) 1 (0.5%) 13 (5.9%)

	Physiotherapy	Arthroscopic Surgery	Total
Bone Average Alpha Angle	66.8 (SD 11.8) Range 43, 93 n=95	67.4 (SD 12.5) Range 43, 112 n=94	67.1 (SD 12.2) Range 43, 112
Bone Maximum Alpha Angle	86.4 (SD 16.9) Range 46, 128 n=95	85.9 (SD 17.1) Range 47, 120 n=94	86.1 (SD 17.0) Range 46, 128
Cartilage Average Alpha Angle	67.2 (SD 10.8) Range 47, 90 n=95	67.4 (SD 11.5) Range 46, 110 n=94	67.3 (SD 11.1) Range 46, 110
Cartilage Maximum Alpha Angle	86.3 (SD 15.5) Range 50, 120 n=95	85.6 (SD15.4) Range 49, 118 n=94	86.0 (SD 15.4) Range 49, 120
Lateral Centre Edge Angle	29.2 (SD 6.7) Range 13, 51 n=105	28.5 (SD 6.8) Range 15, 53 n=106	28.8 (SD 6.8) Range 13, 53

	Physiotherapy	Arthroscopic Surgery	Total
Kellgren Lawrence Grade			
KL grade 0	87 (79.1%)	90 (80.4%)	177 (79.7%)
KL grade 1	18 (16.4%)	16 (14.3%)	34 (15.3%)
No radiograph available	5 (4.5%)	6 (5.4%)	11 (5.0%)

In the arthroscopic surgery group, 99 (88%) participants received their allocated treatment. In the physiotherapy group, 96 (87%) of patients commenced, and 91 (83%) of patients completed, their allocated treatment (Table 2 and Figure 3). Of the 19 patients that did not complete their allocated physiotherapy programme, eight withdrew from the study prior to intervention and two withdrew after the first session of physiotherapy, three patients were not contactable after randomisation, three decided to stop physiotherapy after commencing treatment and subsequently received arthroscopic surgery, and three failed to attend any of their physiotherapy appointments.

133 participants (47 arthroscopic surgery and 86 physiotherapy) commenced treatment within 12 weeks of randomisation and were assessed at 8 months post randomisation. Intervention commenced 12 weeks or more after randomisation for 62 participants (52 arthroscopic surgery and 10 physiotherapy) and outcomes were measured eight months post randomisation and six months post intervention. The significant proportion of patients who commenced treatment after 12 weeks reflected increased NHS waiting times within the duration of this study. The median time from randomisation to surgery in the arthroscopic surgery group was 86 days and from randomisation to the first appointment in the physiotherapy group was 44 days (Table 2).

Table 2: Details of Participants Commencing Allocated Intervention

	Arthroscopic Surgery (n=99)		Physiotherapy (n=96)~	
Average time from randomisation to surgery or commence physiotherapy (days)^	86	IQR: 59-132, Range: 5-435	44	IQR 33-61, Range 14-251
Physiotherapy Intervention*:				
Average number of physiotherapy sessions attended^			6	IQR 4-8, Range 1-8
Average duration of first physiotherapy session (minutes)^			60	IQR 60-60, Range 30-95
Average length of follow-up physiotherapy sessions (minutes)^ (n=83)			30	IQR 30-30, Range 20-60
Surgical Intervention#:				
Labral procedure only$	9	(9.1%)		
Femoral osteochondroplasty	66	(66.7%)		
Acetabular osteochondroplasty (rim-trim)	5	(5.1%)		
Femoral osteochondroplasty + acetabular osteochondroplasty (rim-trim)	19	(19.2%)		
No labral procedure	4	(4.0%)		
Labral repair	70	(70.4%)		
Labral debridement	25	(25.5%)		
No microfracture	90	(90.8%)		
Microfracture	9	(9.2%)		
Average number of physiotherapy sessions attended	4	IQR 2.5-6, Range 1-14		
Average operation time^ (n=77)	55	IQR 45-80, Range 22-160		

~Includes five patients that commenced physiotherapy intervention but did not complete the programme.

*^median #frequency and percentage *information available for 88 of 91 patients who completed physiotherapy.*

$Greater degree of osteoarthritis found at arthroscopy than evident preoperatively and no osteochondroplasty performed in three patients. In six patients there was no evidence of femoroacetabular impingement on intra-operative assessment.

IQR: Interquartile Range

There was complete data for primary analysis on 188 (85%) participants (88 (80%) of individuals randomised to physiotherapy and 100 (89%) of individuals randomised to arthroscopic surgery). Reasons for exclusion of the 34 participants from the primary analysis were loss to follow up for 7 (3%), complete withdrawal from trial for 11 (5%), and incomplete primary end-point data for 16 (7%) (Figure 3).

Participants in the arthroscopic surgery group had a mean HOS ADL score that was 10.0 points (95% CI 6.4 to 13.6, p=0.001) higher than participants in the physiotherapy group at eight months post randomisation. This mean difference was statistically significant and exceeded the pre-specified minimum clinically important difference of nine points, although the lower boundary of the confidence interval was less than nine points (Table 3 and Figure 4). Eight month post randomisation HOS ADL scores were higher than baseline in 70% (95% CI 60 to 78%) patients allocated to arthroscopic surgery compared with 50% (95% CI 40 to 60%) patients allocated to physiotherapy. Clinically important improvement within the individual, defined as an increase in HOS ADL greater than nine points, was reported in 51% (95% CI 41 to 61%) of patients allocated to arthroscopic surgery and 32% (95% CI 22 to 42%) of patients allocated to physiotherapy. A Patient Acceptable Symptomatic State (PASS), defined as HOS ADL greater than 87 points(26), was achieved in 19% (95% CI 11 to 28%) of patients allocated to physiotherapy and 48% (95% CI 38% to 58%) of patients allocated to arthroscopic surgery eight months post randomisation. The proportion of patients who achieved their 'expectation' HOS ADL eight months post randomisation was 15% (95% CI 23 to 41%) for physiotherapy and 31% (95% CI 9 to 24%) for arthroscopic hip surgery.

All supporting analyses of the HOS ADL, including the per protocol analysis, and analysis using multiple imputation, demonstrated similar results to the primary analysis with slightly increased treatment effects that were also statistically significant (Table 3). Baseline 'expectation' HOS ADL was not statistically significant when included as a covariable in the primary analysis and did not change the treatment effect. The treatment effects were robust even to an extreme missing not at random sensitivity analyses, which considered outcomes for those with missing data that were up to nine points worse than expected in the primary analysis (Figure S2).

Subgroup exploration of binary variables identified no evidence of a differential treatment effect for gender or osteoarthritis grade. The small number of individuals with pincer morphology limited the ability to compare outcomes for different FAI type (pincer versus cam versus mixed) (Figure S3). There was a suggestion of an interaction between treatment and baseline age, with a decreasing difference in treatment effect between arthroscopic surgery and physiotherapy with increasing age (Table S3 and Figure S4). Baseline HOS ADL did not appear to influence the differential treatment effect between groups (Table S3 and Figure S5).

Eight-month post-randomisation secondary PROM scores including HOS Sports subscale, NAHS, OHS, iHOT, HAGOS, UCLA, PainDetect, EQ5D and HADS depression score were significantly higher in participants who received arthroscopic surgery compared with physiotherapy (p <0.05) (Table 4). However, there was no significant difference in the HADS anxiety score between treatment groups (p = 0.184).

Patients allocated to arthroscopic surgery had a greater range of hip flexion compared with physiotherapy eight months post randomisation, although there was no statistically significant difference for other movements (Table 5). A smaller proportion of patients allocated to arthroscopic hip surgery reported pain on hip flexion at follow-up compared with physiotherapy, as was also found for hip abduction, adduction, and FAbER, but not FAdIR (Table 6).

At eight-month follow up, two patients crossed over to receive arthroscopic surgery on reporting no improvement in their symptoms after physiotherapy intervention (in addition to four patients who were allocated physiotherapy but received arthroscopic surgery prior to completing their physiotherapy programme). A further patient in the physiotherapy group was referred to the chronic pain service. Complications occurred in three (3%) patients in the arthroscopic surgery group. Superficial wound infection was reported for one patient 12 days after surgery that resolved with oral antibiotics. Injury to the lateral cutaneous nerve of the thigh was reported for two patients, that had resolved in one patient at eight-month follow-up. No participant had serious adverse events related to the trial intervention or trial procedure.

Table 3: Primary and Supporting Analyses

	Physiotherapy			Arthroscopic Surgery			Arthroscopic Surgery versus Physiotherapy		
	Mean	Standard Deviation	Number of Patients	Mean	Standard Deviation	Number of Patients	Adjusted† Treatment Effect	95% Confidence Intervals	p-value
Primary analysis: HOS at 8 months post randomisation	69.2	19.1	88	78.4	19.9	100	10.0	6.4 to 13.6	0.001
Supporting analysis A: Multilevel mixed-effects model*	-			-			10.5	6.4 to 14.6	<0.001
Supporting analysis B: Additional adjustment^	69	19.5	77	80.1	18.7	83	11.7	9.4 to 14.1	0.001
Supporting analysis C: Per protocol population$	69.7	18.6	81	80.5	18.9	79	11.9	6.2 to 17.5	0.002
Supporting analysis D: Post intervention analysis%	69.2	19.3	87	80.4	19.6	91	12.0	7.3 to 16.7	0.001
Multiple imputation analysis	68	20.2	110	78.4	20.3	112	10.0	5.3 to 14.7	0.004

All analysis models are adjusted for baseline HOS ADL (continuous), gender, age at randomisation (continuous) and site (using cluster robust standard errors).

*Multilevel mixed-effects model adjusted for baseline HOS ADL, gender and age at randomisation, time from randomisation (continuous), together with a quadratic term. Participant and randomising site are used as random effects. Data measured up to ten months post randomisation included in the analysis. This analysis includes 330 observations from 191 participants.

^Primary analysis repeated with additional covariates: centre edge angle (continuous), maximum alpha angle (continuous), Kellgren-Lawrence grade (categorical variable with values 0 and 1), and HADS score (anxiety and depression subscales (continuous).

$ Primary analysis repeated for the per protocol population (participants who received their allocated intervention at least eight weeks prior to eight-months post randomisation assessment).

%Primary analysis repeated substituting the eight month post randomisation HOS ADL with the six month post intervention HOS ADL in patients where the time from randomisation to intervention exceeded 12 weeks.

Table 4: Secondary PROMs Analysis

	Physiotherapy Number of participants (number of observations)	Arthroscopic Surgery Number of participants (number of observations)	Arthroscopic Surgery versus Physiotherapy Adjusted† Treatment effect (95%CI)		p-value†
HOS Sports subscale[1]	91 (166)	99 (163)	11.7	(5.8 to 17.6)	<0.001
OHS[1]	87 (160)	92 (153)	5.3	(3.2 to 7.5)	<0.001
NAHS[1]	78 (139)	91 (147)	11.2	(6.8 to 15.7)	<0.001
iHOT[1]	88 (162)	92 (155)	2.0	(1.3 to 2.8)	<0.001
HAGOS Symptoms[1]	88 (161)	92 (155)	13.3	(8.1 to 18.6)	<0.001
HAGOS Pain[1]	88 (161)	92 (154)	12.7	(8.1 to 17.2)	<0.001
HAGOS ADL[1]	88 (162)	92 (154)	11.6	(6.7 to 16.6)	<0.001
HAGOS Sport[1]	88 (161)	92 (155)	13.1	(7 to 19.1)	<0.001
HAGOS PA[1]	88 (162)	91 (153)	14.6	(7.2 to 22)	<0.001
HAGOS QoL[1]	88 (162)	91 (154)	13.2	(7.5 to 19)	<0.001
UCLA[1]	88 (162)	92 (155)	0.6	(0.1 to 1)	0.01
PainDetect Score[2]	62 (101)	61 (93)	-2.1	(-4 to -0.2)	0.03
HADS anxiety[2]	88 (162)	91 (153)	-0.6	(-1.4 to 0.3)	0.18
HADS depression[2]	88 (162)	91 (153)	-1.3	(-2.2 to -0.4)	0.004
EQ-5D-3L index[1]	88 (161)	91 (153)	0.1	(0 to 0.1)	0.003
EQ-5D-3L VAS[1]	85 (153)	86 (145)	0.7	(0.3 to 1.2)	0.002

†Multilevel mixed-effects model for mITT population adjusted for baseline HOS ADL, gender and age at randomisation, time from randomisation (continuous), together with a quadratic term. Participant and randomising site are used as random effects. Data measured up to ten months post randomisation included in the analysis.
[1]For this PROM, higher values indicate better outcomes. [2]For this PROM, lower values indicate better outcomes.

Table 5 : Range of Hip Movement at Baseline and Eight Month Post Randomisation Assessment						
	Physiotherapy Baseline	Physiotherapy 8 Month Assessment	Arthroscopic Surgery Baseline	Arthroscopic Surgery 8 Month Assessment	Difference in ROM Adjusted for Baseline	Statistical Significance$
Hip Flexion	95.7 (SD 19.1) Range 27, 126 n=107	99.7 (SD 17.5) Range 25, 130) n=85	96.9 (SD 15.8) Range 50, 130 n=111	105.8 (SD 16.3) Range 40, 138 n=96	4.8 (95% CI 0.5 to 9.1)	p=0.03
Hip Extension	17.9 (SD 7.9) Range 5, 50 n=100	15.7 (SD 8.0) Range 0, 46) n=83	18.2 (SD 8.0) Range 0, 40 n=104	16.8 (SD 7.4) Range 0, 45) n=96	1.6 (95% CI -0.6 to 3.8)	p=0.16
Hip Abduction	27.5 (SD 11.9) Range 5, 60 n=107	29.6 (SD 11.7) Range 5, 70 n=84	27.1 (SD 12.0) Range 5, 80 n=110	30.3 (SD 10.6) Range 8, 66 n=96	1.0 (95% CI -2.1 to 4.1)	p=0.53
Hip Adduction	21.6 (SD 7.9) Range 5, 44 n=104	23.2 (SD 8.9) Range 5, 50 n=84	20.9 (SD 8.2) Range 5, 60 n=108	23.9 (SD 8.2) Range 9, 45 n=96	1.1 (95% CI -1.2 to 3.5)	p=0.35
Hip Internal Rotation	24.0 (SD 11.2) Range 5, 55 n=107	28.9 (SD 11.2) Range 2, 55 n=84	24.9 (SD 11.2) Range 2, 56 n=110	30.8 (SD 10.6) Range 5, 69 n=96	1.4 (95% CI -1.6 to 4.4)	p=0.37
Hip External Rotation	25.0 (SD 11.8) Range 5, 80 n=107	27.4 (SD 9.7) Range 8, 70 n=84	26.2 (SD 10.6) Range 7, 80 n=110	27.0 (SD 8.9) Range 10, 50 n=96	-1.1 (95% CI -3.6 to 1.4)	p=0.38

$ Wilcoxon Rank-Sum Test

ROM: Range of Movement, SD: Standard Deviation, CI: Confidence Interval

Table 6 – Hip Assessment at Baseline and Eight Month Post Randomisation						
		Physiotherapy Baseline^	Physiotherapy 8 Month Assessment^	Arthroscopic Surgery Baseline^	Arthroscopic Surgery 8 Month Assessment^	Statistical Significance$
Pain on Flexion	Yes	77 (70.0%)	56 (50.9%)	80 (71.4%)	46 (41.1%)	p=0.01
	No	31 (28.2%)	29 (26.4%)	31 (27.7%)	51 (45.5%)	

	Not Available	2 (1.8%)	25 (22.7%)	1 (0.9%)	15 (13.4%)	
Pain on Extension	Yes	44 (40%)	24 (21.8%)	41 (36.6%)	18 (16.1%)	
	No	61 (55.5%)	59 (53.6%)	67 (59.8%)	79 (70.5%)	p=0.10
	Not Available	5 (4.5%)	27 (24.5%)	4 (3.6%)	15 (13.4%)	
Pain on Abduction	Yes	72 (65.5%)	48 (43.6%)	74 (66.1%)	41 (36.6%)	
	No	36 (32.7%)	36 (32.7%)	38 (33.9%)	56 (50.0%)	p=0.05
	Not Available	2 (1.8%)	26 (23.6%)	0 (0%)	15 (13.4%)	
Pain on Adduction	Yes	51 (46.4%)	39 (35.5%)	61 (54.5%)	30 (26.8%)	
	No	55 (50.0%)	45 (40.9%)	50 (44.6%)	67 (59.8%)	p=0.03
	Not Available	4 (3.6%)	26 (23.6%)	1 (0.9%)	15 (13.4%)	
Pain on Internal Rotation	Yes	78 (70.9%)	47 (42.7%)	77 (68.8%)	44 (39.3%)	
	No	30 (27.3%)	37 (33.6%)	34 (30.4%)	53 (47.3%)	p=0.16
	Not Available	2 (1.8%)	26 (23.6%)	1 (0.9%)	15 (13.4%)	
Pain on External Rotation	Yes	55 (50.0%)	33 (30.0%)	50 (44.6%)	30 (26.8%)	
	No	53 (48.2%)	51 (46.4%)	61 (54.5%)	67 (59.8%)	p=0.24
	Not Available	2 (1.8%)	26 (23.6%)	1 (0.9%)	15 (13.4%)	
FAdIR Test	Positive	95 (86.4%)	66 (60.0%)	103 (92%)	70 (62.5%)	
	Negative	11 (10.0%)	18 (16.4%)	9 (8.0%)	26 (23.2%)	p=0.38
	Not Available	4 (3.6%)	26 (23.6%)	0 (0%)	16 (14.3%)	
FAbER Test	Positive	89 (80.9%)	52 (47.3%)	91 (81.3%)	42 (37.5%)	
	Negative	18 (16.4%)	32 (29.1%)	21 (18.8%)	54 (48.2%)	p=0.02
	Not Available	3 (2.7%)	26 (23.6%)	0 (0%)	16 (14.3%)	

FAdIR Test = Pain on Flexion, Adduction, Internal Rotation. FAbER Test = Pain on Flexion, Abduction, External Rotation. ^Frequency (Percentage)
$Chi Square Test for association between outcomes eight months post randomisation

Discussion:

Principal Findings:

The results of this trial demonstrate that patients with symptomatic FAI experience a greater improvement in symptoms with arthroscopic hip surgery compared with physiotherapy and activity modification eight months post randomisation. The 10 point mean difference in HOS ADL between groups is greater than the pre-specified minimum clinically important difference of nine points, however, the lower boundary of the confidence interval is less than this nine point threshold for clinical importance. In this cohort, the difference in HOS ADL between treatment groups is expected to lie between 6.4 and 13.6 points in favour of arthroscopy.

Within the individual, 51% of patients randomised to arthroscopic hip surgery and 32% of patients randomised to physiotherapy reported an improvement in HOS ADL that exceeded nine points (minimum detectable change and a clinically important change within an individual). In addition, 48% of patients randomised to arthroscopic hip surgery and 19% of patients randomised to physiotherapy achieved the PASS after treatment.

Blinded clinical assessments revealed a greater improvement in the range of hip flexion and associated discomfort in patients allocated to arthroscopic surgery compared with physiotherapy. Additional patient reported outcome measures also indicated improved outcomes in patients randomised to arthroscopic hip surgery.

Comparison with Other Studies:

Two other randomised controlled trials comparing physiotherapy rehabilitation with arthroscopic surgery for symptomatic FAI were published in 2018 with comparable protocols to this study. Mansell et al. did not find a difference between arthroscopic surgery and physiotherapy at any time point up to two-year follow-up, although there was a 70% cross-over from allocated physiotherapy to arthroscopic surgery(8). Griffin et al. concluded that arthroscopic surgery was superior to best conservative care at improving symptoms

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at 12-month follow-up, but not cost-effective(27). Contrary to our study, they did not find differences between treatment groups for secondary outcome measures of general health-related quality of life (EQ-5D and SF-12). Arthroscopic surgery and physiotherapy are safe and the low complication rates found in this trial are consistent with other studies(7, 28). The age and gender of patients recruited reflected national trends in the provision of arthroscopic hip surgery(10).

Strengths and Limitations:

Surgery was performed by consultant orthopaedic surgeons with a specialist interest in the young adult hip, which reflects the provision of hip arthroscopy in the NHS and recommendations from the National Institute for Health and Care Excellence (NICE). Participating centres consisted of five District General Hospitals and two University Teaching Hospitals. The delivery of care by surgeons performing a high volume of arthroscopic hip procedures ensured they are beyond the steep learning curve for this surgery, and the risk of complications is higher for surgeons performing a low volume of procedure(29, 30). A limitation of our study is that the majority of patients were recruited from the coordinating centre, however, the treatment effect was consistent for centres recruiting more than 20 patients (Figure S3).

Physiotherapy was delivered by physiotherapists of different seniority trained in the study protocol with a maximum of eight sessions. There is very little evidence to guide the development of an optimal physiotherapy protocol. It could be suggested that a greater number and frequency of physiotherapy sessions with only senior specialist physiotherapists may improve outcomes. Our aim was to compare arthroscopic hip surgery with a physiotherapy intervention that is deliverable within the constraints of NHS resources to ensure generalisability and restrict excess treatment costs. Standard commissioning in the NHS limits physiotherapy provision to approximately six sessions of individual physiotherapy and we offered a maximum of eight sessions.

Patients in both treatment groups received physiotherapy, either as their primary intervention, or as post-surgical rehabilitation. It is important to emphasise the difference in these regimes. The focus of physiotherapy for the treatment of FAI syndrome (randomised study intervention) was to improve pain and function. The principal elements of our programme started with activity and movement modification,

followed by muscle strengthening and segmental stabilisation, and finally optimisation of functional movements with sensory motor training and return to activity according to patient goals. This physiotherapy package was delivered over a median of six sessions. The focus of physiotherapy post arthroscopic surgery was to maintain range of movement and guide return to activity. Patients were advised to commence active range of movement and isometric exercises the day following surgery, progressing to stretches and static bicycle exercise (no resistance) within a week. Strengthening exercises and low impact activities were introduced after three weeks, usually under physiotherapist guidance, and impact exercise was permitted after six weeks with sport-specific rehabilitation when appropriate. This physiotherapy package was delivered over a median of four sessions.

The clinical significance of an improved range of hip flexion in patients allocated to arthroscopic surgery compared with physiotherapy is not known. A cohort study of patients receiving arthroscopic hip surgery found that hip flexion was the only movement associated with improved patient reported outcome measures(31). A possible explanation is the functional importance of this movement during everyday activities such as sitting or climbing stairs, when pain is frequently experienced with FAI syndrome. Despite the limitation of performing multiple statistical tests, our results also suggest less pain on hip movements in patients allocated to arthroscopic hip surgery compared with physiotherapy.

Overall, 70% of patients randomised to arthroscopy and 50% of patients randomised to physiotherapy reported an improvement in HOS ADL, however, only half the participants randomised to arthroscopy reported an improvement in HOS ADL exceeding nine points or achieved the PASS. A limitation of reported minimally clinically important differences between groups or changes within an individual is that they are specific to the cohort and methodology researchers used to calculate values. We pre-specified an HOS ADL of nine points as the minimum clinically important difference between groups(15). We also used this value to explore the proportion of patients that achieved a clinically important change in HOS ADL. Since developing the study protocol, the smallest detectable change in HOS ADL within an individual has been calculated as nine points, and the minimum clinically important change in HOS ADL

within an individual as five points(36). This finding supports our use of a nine-point threshold to represent both a clinically important difference between groups and change within an individual.

Whilst arthroscopic hip surgery appears superior to physiotherapy, patients must be informed of the potential risks and benefits of surgery, including the risk of no improvement. Up to a half of patients will not achieve a clinically important improvement after surgery, hence accurate patient selection is critical to optimising treatment outcomes. Increasing patient age, higher pre-operative patient-reported scores, and the presence of osteoarthritis have been identified as having a negative impact on outcome in cohort studies of arthroscopic hip surgery(32-35).

Exploration of subgroups suggested that older patients may gain less benefit from arthroscopic surgery compared with physiotherapy, however, there was large variation in HOS ADL outcome scores across different ages. Further exploration in a larger population is required to determine the effect of age on outcomes. Cohort studies also report that hip arthroscopic surgery is less effective with increasing age(32, 33), however, older patients also experience significant improvements in symptoms(32).

Patients with established osteoarthritis defined as patients with 'osteophytes and possible joint space width narrowing' (Kellgren Lawrence 2) or more severe disease were excluded from the study. Patients with 'possible osteophytes and doubtful narrowing of joint space' (Kellgren-Lawrence 1) were included. Cohort studies suggest that osteoarthritis is only detrimental to outcomes once there is established loss of joint space width(34). In our exploratory evaluation of subgroups we did not detect a difference in treatment effect between individuals with Kellgren-Lawrence 1 disease and those with no radiographic osteoarthritis (Kellgren-Lawrence 0), although our study was not powered for this calculation.

We were unable to explore whether the presence of cam, pincer, or mixed morphology influences treatment effect due to the small number of patients with pincer impingement. The relative proportion of patients with each FAI type in this cohort reflects the general population, but the results of this study may not be generalisable to pincer and mixed morphology FAI. Exploratory analysis within the study population did not find an association between outcome and any morphological hip measurement, including the magnitude of cam or pincer morphology and an interaction term.

The exclusion of patients with dysplasia and osteoarthritis is a potential limitation of the study given these patients may also benefit from arthroscopic hip surgery, however, our inclusion criteria reflect current evidence-based clinical practice(11, 12). We anticipate that advances in imaging will enhance our ability to identify patients most likely to benefit from intervention through enhanced diagnosis of osteoarthritis and dynamic assessment of hip morphology. In this study, intra-operatively three patients were found to have more advanced osteoarthritis than was appreciated preoperatively, and six patients were not found to impinge within a functional range of movement despite the preoperative diagnosis of cam morphology. The planned osteochondroplasty procedure was therefore not performed. Total hip replacement may have been more appropriate in the patients with osteoarthritis.

Psychological factors are likely to influence outcomes from FAI treatment(36) as found for joint arthroplasty(37). Patient expectation was not found to influence treatment effect in this study, but further exploration into the effect of baseline depression and anxiety on outcomes may be of value given cohort studies have demonstrated that they influence outcome(36). The most frequent reason for declining participation was preference for surgery. Four patients randomised to physiotherapy underwent surgery prior to collection of the primary outcome measure. Our results may in part reflect a nocebo effect of physiotherapy and placebo effect of surgery. The placebo effect has been shown to be large in surgical trials of arthroscopic shoulder decompression(38) and arthroscopic meniscectomy(39). Our blinded clinical assessments offer reassurance of a differential treatment effect between groups. An ongoing trial comparing osteochondroplasty with arthroscopic lavage for FAI syndrome may offer further insight into the efficacy of surgical treatment(40).

Median time to treatment post randomisation was 44 days for physiotherapy and 86 days for arthroscopic surgery. Comparing operative and non-operative management is challenging given surgical care is usually delivered at a single timepoint whereas physiotherapy takes place over weeks or months. The longer waiting times for surgery may influence results, however, this is a pragmatic trial and the care delivered accurately reflects current practice in NHS settings. Intention to treat rather than post-intervention analysis was selected as the primary outcome because whereas groups are balanced at the time of randomisation (a requirement for inferring a causal relationship between intervention and outcome), this may not be true

at any other timepoint. We also performed a post-intervention analysis (Supporting Analysis D), which revealed a comparable treatment effect to the mITT analysis (Table 3). There were dropouts in both treatment groups, and although the study remained adequately powered, baseline scores were slightly lower in the physiotherapy group (Table S2). Nevertheless, our primary analysis adjusts for prognostic factors and the treatment effect was robust to different assumptions regarding missing data (missing at random and missing not at random) in our sensitivity analysis (Figure S2).

This trial does not capture patients with minimally symptomatic FAI, who are typically diagnosed and treated in primary care. Instead it provides guidance for the treatment of patients who are referred to secondary or tertiary care with more severe or prolonged symptoms. Given the potential complications of surgery and observed clinical improvement with physiotherapy and activity modification, we currently recommend this intervention as first-line treatment. If symptoms continue then the likelihood of symptom improvement with arthroscopic hip surgery should be given consideration.

Conclusions and Policy Implications:

The results of this study suggest that patients with symptomatic FAI referred to secondary or tertiary care achieve a greater improvement in patient reported outcomes with arthroscopic hip surgery compared with non-operative measures. However, further research is required to identify patients most likely to benefit from intervention. The evaluation of treatment cost-effectiveness and disease-modifying potential with long-term follow-up of this cohort will further guide treatment and commissioning decisions.

Oversight Committees:

Trial Steering Committee: Mr Oliver Pearce (Consultant Orthopaedic Surgeon, Milton Keynes University Hospital NHS Foundation Trust), Mr Timothy Theologis (Consultant Orthopaedic Surgeon, Oxford University Hospitals NHS Foundation Trust), Mr Sunil Auplish (Consultant Orthopaedic Surgeon, Barking, Havering and Redbridge University Hospitals NHS Trust). Data Monitoring Committee: Dr Karen Smith (Principal Statistician, NIHR Research Design Services, University of Leicester), Mr Muthu Ganapathi (Consultant Orthopaedic Surgeon, NHS Wales University Health Board). Mr Peter Lovell (Lay Representative).

Contributors:

AJRP and SGJ designed the study and the protocol was developed with VAG, IR, SJD, SW, TCBP, AWM, KLB, AJMDA, AJC, and DJB. IR and SJD performed the statistical analyses. AJRP, VAG, SF, RM, SW, VK, TCBP, AJMDA, and SGJ recruited patients and acquired data. AJRP, VAG, SF, IR, and SGJ drafted the manuscript. All authors revised manuscript drafts, approved the final manuscript, and contributed intellectually important content. SGJ attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. SGJ is the guarantor of the paper and takes responsibility for the integrity of the work from inception to published article.

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Data sharing:

Anonymised patient level data can be made available on reasonable request after approval from the trial management committee and after signing a data access agreement. Proposals should be directed to the corresponding author. Consent was not obtained for data sharing but the presented data is anonymised and the risk of identification is low.

Transparency:

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Figure Legends:

Figure 1. Anteroposterior radiographs demonstrating a) normal morphology b) cam morphology, and c) pincer morphology. Bone outlined in yellow represents abnormal morphology that predisposes to FAI, and is excised with a burr during arthroscopic surgery to prevent impingement.

Figure 2: Right hip coronal MRI of trial participant randomised to surgery: (A) Baseline image demonstrating cam morphology (white arrow). (B) Six months post hip arthroscopy with restoration of the normal concavity at the femoral head-neck junction by burring away the cam lesion (white arrow). This procedure prevents abutment of the femoral head-neck junction against the acetabular rim during a functional range of movement.

Figure 3: CONSORT Diagram

Figure 4: Box and Whisker Plot for HOS ADL at baseline and eight months post randomisation follow up (mITT).

Print Abstract:

Study Questions: Is arthroscopic hip surgery superior to physiotherapy and activity modification for improving patient reported outcome measures in patients with symptomatic femoroacetabular impingement (FAI)?

Methods: The Femoroacetabular Impingement Trial (FAIT) is a two-group parallel, assessor-blinded, pragmatic randomised controlled study in secondary and tertiary care centres across seven NHS England

sites. 222 participants aged 18 to 60 years with symptomatic FAI confirmed clinically and radiologically were randomised (1:1) to receive arthroscopic hip surgery (n = 112) or physiotherapy (n = 110). Exclusion criteria included previous surgery, completion of a physiotherapy programme targeting FAI within the preceding 12 months, established osteoarthritis, and hip dysplasia. Participants in the physiotherapy group received an individualised goal-based programme with emphasis on improving core stability and movement control. Up to eight physiotherapy sessions were delivered over five months. Participants in the arthroscopic hip surgery group received surgery to excise the bone that impinged during hip movements, followed by routine post-operative care. The primary outcome measure was the Hip Outcome Score Activities of Daily Living (HOS ADL) at eight months post-randomisation with a pre-specified minimum clinically important difference of nine points.

Study Answer: At eight months post-randomisation, mean HOS ADL was 10.0 points higher in the arthroscopic hip surgery group compared with the physiotherapy and activity modification group (95% CI 6.4 to 13.6, p<0.001). Limitations include an overall drop-out rate of 15%, however, study conclusions were unchanged after sensitivity analyses for missing data.

What This Study Adds: The results suggest that arthroscopic hip surgery is superior to physiotherapy and activity modification at improving patient reported outcome measures in patients referred to secondary or tertiary care with symptomatic FAI.

Trial Registration: ClinicalTrials.gov: NCT01893034.

Funding: Arthritis Research UK and National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC).

Conflicts of Interest: None declared.

Data Sharing: Available on request.

Figure Legend: Graphs demonstrating the direction and magnitude of change in HOS ADL between baseline and eight months post randomisation for each participant.