

Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial



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Summary

Background Femoroacetabular impingement syndrome is an important cause of hip pain in young adults. It can be treated by arthroscopic hip surgery, including reshaping the hip, or with physiotherapist-led conservative care. We aimed to compare the clinical effectiveness of hip arthroscopy with best conservative care.

Methods UK FASHIoN is a pragmatic, multicentre, assessor-blinded randomised controlled trial, done at 23 National Health Service hospitals in the UK. We enrolled patients with femoroacetabular impingement syndrome who presented at these hospitals. Eligible patients were at least 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. Patients with bilateral femoroacetabular impingement syndrome were eligible; only the most symptomatic hip was randomly assigned to treatment and followed-up. Participants were randomly allocated (1:1) to receive hip arthroscopy or personalised hip therapy (an individualised, supervised, and progressive physiotherapist-led programme of conservative care). Randomisation was stratified by impingement type and recruiting centre and was done by research staff at each hospital, using a central telephone randomisation service. Patients and treating clinicians were not masked to treatment allocation, but researchers who collected the outcome assessments and analysed the results were masked. The primary outcome was hip-related quality of life, as measured by the patient-reported International Hip Outcome Tool (iHOT-33) 12 months after randomisation, and analysed in all eligible participants who were allocated to treatment (the intention-to-treat population). This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN64081839, and is closed to recruitment.

Findings Between July 20, 2012, and July 15, 2016, we identified 648 eligible patients and recruited 348 participants: 171 participants were allocated to receive hip arthroscopy and 177 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% (319 of 348 participants). At 12 months after randomisation, mean iHOT-33 scores had improved from 39.2 (SD 20.9) to 58.8 (27.2) for participants in the hip arthroscopy group, and from 35.6 (18.2) to 49.7 (25.5) in the personalised hip therapy group. In the primary analysis, the mean difference in iHOT-33 scores, adjusted for impingement type, sex, baseline iHOT-33 score, and centre, was 6.8 (95% CI 1.7–12.0) in favour of hip arthroscopy ($p=0.0093$). This estimate of treatment effect exceeded the minimum clinically important difference (6.1 points). There were 147 patient-reported adverse events (in 100 [72%] of 138 patients) in the hip arthroscopy group versus 102 events (in 88 [60%] of 146 patients) in the personalised hip therapy group, with muscle soreness being the most common of these (58 [42%] vs 69 [47%]). There were seven serious adverse events reported by participating hospitals. Five (83%) of six serious adverse events in the hip arthroscopy group were related to treatment, and the one in the personalised hip therapy group was not. There were no treatment-related deaths, but one patient in the hip arthroscopy group developed a hip joint infection after surgery.

Interpretation 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 than did personalised hip therapy, and this difference was clinically significant. Further follow-up will reveal whether the clinical benefits of hip arthroscopy are maintained and whether it is cost effective in the long term.

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Introduction

Femoroacetabular impingement syndrome is a painful disorder of the hip that is caused by a premature contact

(impingement) between the femur and acetabulum during hip movements.^{1,2} This premature contact typically occurs as a result of certain hip shapes, such as cam or pincer

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Research in context

Evidence before this study

Femoroacetabular impingement syndrome is a relatively common non-arthritis cause of hip pain in young adults. It is caused by symptomatic premature contact between the proximal femur and acetabular rim during hip motion, and this phenomenon is associated with certain hip shapes. Repeated impingement leads to damage to the articular cartilage or to acetabular labral tears, and it is these injuries that are thought to be painful. In the past decade, surgeons have developed arthroscopic (ie, keyhole) surgical techniques to treat femoroacetabular impingement syndrome. The rationale is that reshaping the hip and repairing cartilage and labral damage will prevent impingement and relieve symptoms. In 2013, we did a Cochrane systematic review of the effectiveness of hip arthroscopy for femoroacetabular impingement syndrome. We searched MEDLINE (from 1946 to Nov 19, 2013), Embase (1980 to Nov 19, 2013), and the Cochrane Central Register of Controlled Trials (issue 11, 2013), for randomised controlled trials of surgery compared with placebo treatment, non-operative treatment, or no treatment, in any language, in human adults with femoroacetabular impingement syndrome. We found no high-quality evidence examining the effectiveness of surgery for femoroacetabular impingement syndrome. Therefore, we chose to do a pragmatic, multicentre, randomised controlled trial to

determine the effectiveness of hip arthroscopy compared with best conservative care.

Added value of this study

To our knowledge, this is the largest randomised controlled trial to show the clinical effectiveness of hip arthroscopy in treating femoroacetabular impingement syndrome. We have shown that patients with femoroacetabular impingement syndrome have better hip-related quality of life at 12 months since randomisation with either hip arthroscopy or best conservative care (personalised hip therapy), and that this quality of life improves significantly more in patients treated hip arthroscopy, exceeding the minimal clinically important difference. Hip arthroscopy was also more expensive than was personalised hip therapy.

Implications of all the available evidence

Over the past 15 years, increasing numbers of patients with femoroacetabular impingement syndrome have been treated with hip arthroscopy. This is the first study to show that hip arthroscopy is more clinically effective, at least in the short term, than best conservative care. Longer-term outcomes are required to establish whether this improvement is sustained and whether surgery is cost-effective. These results should be shared with patients when selecting an appropriate treatment strategy.

morphology.¹ Cam morphology refers to a flattening or convexity at the femoral head neck junction, whereas pincer morphology refers to a focal or global over-coverage of the femoral head by the acetabulum.¹ Femoroacetabular impingement syndrome leads to progressive damage within the joint, including the acetabular labrum and articular cartilage,¹ and is associated with the development of osteoarthritis of the hip.^{1,3}

Surgery has become an established treatment for femoroacetabular impingement syndrome. The aim of such surgery is to reshape the hip joint to prevent impingement.² Intra-articular injury, such as a cartilage and labral damage, can be resected, repaired, or reconstructed.² Initially, open surgery was used to treat femoroacetabular impingement syndrome, but the minimally invasive, so-called keyhole technique known as hip arthroscopy is now being used more frequently.¹ This approach has become possible because of advances in technology and surgical techniques. Hip arthroscopy is safer and has a shorter recovery time than does open surgery.^{4,5} In the UK in 2013, 1908 operations for femoroacetabular impingement syndrome were done by arthroscopic surgery, compared with only 491 by open surgery.⁶ Since then, there has been a rapid increase in the use of hip arthroscopy in most countries around the world.^{4,6} Non-operative treatments for femoroacetabular impingement syndrome are also available,² including exercise-based packages of conservative care, delivered by

a physiotherapist.⁷ Potential targets for physiotherapy include the abnormal movement patterns and weakness of hip muscles seen in patients with femoroacetabular impingement syndrome.^{8,9}

Numerous case series report improvement in patients with femoroacetabular impingement syndrome after open or arthroscopic surgery, or physiotherapy.^{5,10} However, a 2014 Cochrane review¹¹ of surgery for treating femoroacetabular impingement syndrome showed that there was no evidence from randomised controlled trials to support these treatments.

In a feasibility study,⁶ we established that patients were prepared to be recruited, and that surgeons were in equipoise and willing to recruit patients to a randomised controlled trial of hip arthroscopy compared with best conservative care. Our aim was to measure the clinical effectiveness of hip arthroscopy compared with best conservative care in treating patients with femoroacetabular impingement syndrome.

Methods

Study design and participants

We did this pragmatic, multicentre, assessor-blind randomised controlled trial in 23 National Health Service (NHS) hospitals in the UK. We treated the initial feasibility study⁶ as an internal pilot study so that participants who took part in the initial study were included in the main trial recruitment.

Participants were recruited from the specialist hip arthroscopy service at each hospital. Participating surgeons identified eligible patients during routine diagnostic consultations. Assessments were medical history, clinical examination, X-rays, and cross-sectional imaging (MRI, CT, or both). For patients with a diagnosis of femoroacetabular impingement syndrome, the surgeon classified them as having cam (alpha angle $>55^\circ$), pincer (lateral centre-edge angle $>40^\circ$ or a positive crossover sign), or mixed-type (combination of cam and pincer) impingement.¹²

Patients were eligible if they had hip pain, radiographic features of cam or pincer morphology, were at least 16 years old, 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 (Tonnis grade >1 or less than 2 mm of superior joint space on an antero-posterior radiograph); a history of hip pathology such as Perthes' disease, slipped upper femoral epiphysis, or avascular necrosis, or previous hip injury such as acetabular fracture, hip dislocation, or femoral neck fracture; or if they had already had shape-changing surgery (open or arthroscopic) of the hip.^{13,14} Patients with bilateral femoroacetabular impingement syndrome were eligible, and only the most symptomatic hip was randomly assigned to treatment and followed up. Trained research associates approached eligible patients to explain the trial and to invite them to participate. All participants gave written informed consent.

Qualitative research, to understand recruitment as it occurred, was integrated into the trial. The findings were used to design a recruiter training and centre support programme that was implemented during the trial to optimise recruitment. The research was based on the QuinteT Recruitment Intervention and continued the work done during the internal pilot trial.^{15,16}

The study was approved by NHS Research Ethics Service West Midlands (14/WM/0124). An independent trial steering committee and data monitoring committee provided oversight of the progression of the study. The study protocol has previously been published.¹⁷

Randomisation and masking

Participants were randomly assigned (1:1) with a computer-generated minimisation (adaptive stratified sampling) algorithm for centre and type of impingement, to receive either hip arthroscopy or best conservative care. All baseline data were collected before randomisation, which was done by the recruiting research associate. Allocation concealment was ensured by use of a secure telephone randomisation service hosted by Warwick Clinical Trials Unit. It was not possible to mask patients or the treating clinicians to their allocation. Researchers who collected outcome assessments and analysed the results were masked to allocation by concealment of treatment.

Procedures

Surgery for femoroacetabular impingement syndrome was done using arthroscopic techniques by a senior surgeon (consultant grade) in the NHS, who was trained and experienced in hip arthroscopy. Further details about surgeons' training and experience, and surgical procedures are shown in the appendix. 27 trial surgeons did the surgery. Hip arthroscopy was done under general anaesthesia in a lateral or supine position. Arthroscopic portals were established in the central and peripheral compartments of the hip under radiographic guidance according to the surgeon's usual practice. 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 allowed home when they could walk safely with crutches (typically within 24 h). Patients were referred to outpatient physiotherapy services for a course of rehabilitation as per usual care for that surgeon. These post-operative physiotherapists were distinct from those providing conservative care, to avoid contamination between groups. Patients had MRI of their hip at least 6 weeks after surgery.

A panel of international experts assessed the fidelity of the surgery (appendix). They reviewed operation notes, intraoperative images, and postoperative MRI scans to subjectively assess whether adequate surgery had been undertaken, according to the protocol. The panel discussed each case and subjectively assessed whether shape abnormalities and intra-articular pathology were treated, and whether there was a sufficient resection to allow impingement-free range of motion. This approach included assessing the proximal femoral and acetabular rim resections and whether the resection edges were smooth.

Personalised hip therapy is a package of physiotherapist-led rehabilitation for femoroacetabular impingement syndrome. It was developed during our feasibility study and tested during the pilot study.⁶ Although the name for this intervention is new, the care offered was based on a consensus of what physiotherapists, physicians, and surgeons currently regard as best conservative care for femoroacetabular impingement syndrome.⁷ Personalised hip therapy has four core components: an assessment of pain, function, and range of hip motion; patient education; an exercise programme taught in the clinic and repeated at home, that has the key features of individualisation, progression, and supervision; and help with pain relief, which could include one X-ray or ultrasound-guided intra-articular steroid injection when pain prevents performance of the exercise programme.¹⁸

Personalised hip therapy was delivered by at least one physiotherapist at each centre. 47 physiotherapists were trained formally in this protocol through a 1-day

See Online for appendix

For the study protocol see <http://bmjopen.bmj.com/content/6/8/e012453>

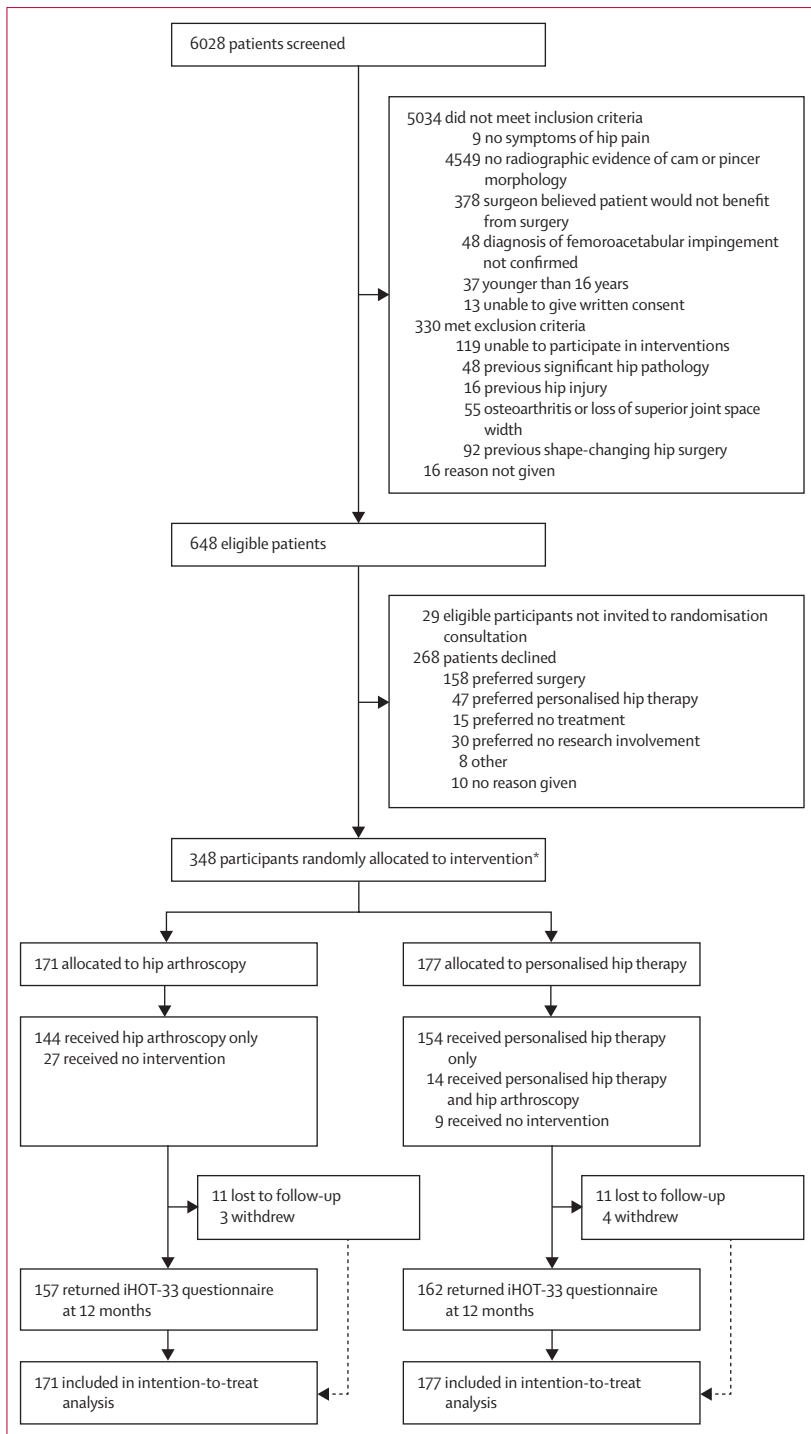


Figure 1: Trial profile

iHOT-33=International Hip Outcome Tool. *Three patients were randomly assigned in error but did not receive treatment and were not followed-up.

workshop and supported to deliver personalised hip therapy through refresher workshops (appendix). At their initial assessment, participants received a personalised hip therapy information pack that

described what to expect during the course of their treatment. They then had between six and ten face-to-face contacts with the physiotherapist over 12–24 weeks. Some contacts were allowed by either telephone or email when geographical distance prevented all contacts being carried out face-to-face. Patient-completed exercise diaries were also encouraged to help both patients and physiotherapists monitor progress and adherence with personalised hip therapy.

Physiotherapists recorded full details of their advice and treatments, number and type of treatment contacts, and any non-attendance, on case report forms. These case report forms were reviewed for accuracy in comparison to the usual physiotherapy records at each treatment centre and then assessed for fidelity to the personalised hip therapy protocol by a panel comprising members of the core group who developed the protocol for personalised hip therapy (appendix). The personalised hip therapy panel reviewed case report forms to ensure participants received an adequate number of sessions, all four core components, and that their exercise programme was individualised, supervised, and progressive.

Outcomes

The primary outcome was hip-related quality of life, as measured by the international Hip Outcome Tool (iHOT-33) at 12 months after randomisation.¹⁹ iHOT-33 is a patient-derived and patient-reported outcome instrument designed to measure hip-related quality of life in young adults with non-arthritic hip pain. The iHOT-33 consists of four domains: symptoms and functional limitations; sports and recreational physical activities; job-related concerns; and social, emotional, and lifestyle concerns.¹⁸ iHOT-33 provides a 100-point score, with 100 representing no pain and perfect function, and lower scores indicating pain and poor function. The instrument has been validated in a relevant population for this trial,¹⁹ and has a minimum clinically important difference of 6.1 points.^{19,20} Secondary outcomes were health-related quality of life, measured with the EuroQol EQ-5D-5L, the 12-item Short Form Health Survey (SF-12 version 2), adverse events, and health-care resource use, all measured 6 and 12 months after treatment allocation.^{21–23} Patients reported adverse events 6 weeks after the start of their intervention (first session of personalised hip therapy, or date of hip arthroscopy). Any serious adverse events were reported by each centre to the Warwick Clinical Trials Unit. Forms for iHOT-33, EQ-5D-5L, SF-12, adverse events, and health-care resource use were collected by postal questionnaires, which were centrally administered. Scores for these measures were collected at the time of consent and again by postal questionnaire at 6 and 12 months after treatment allocation.

Statistical analysis

The planned sample size was 172 participants in each group, based on a standard deviation of iHOT-33 of

16 points and a minimum clinically important difference 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 timepoint.

We prepared a full statistical analysis plan before the final analysis. No interim analyses were planned. The plan was approved by the independent data monitoring committee.

In our primary analysis, we investigated differences in the primary outcome measure, (iHOT-33 score at 12 months after randomisation) between the two treatment groups on an intention-to-treat basis, which included all eligible patients randomly assigned to an intervention. We assessed the primary outcome 12 months from treatment allocation rather than from intervention because this was a pragmatic trial design of two different treatment strategies. We used a mixed-effects regression analysis 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. This mixed-effects model was used for all outcome measures.

We drew our primary inferences from the intention-to-treat analysis, irrespective of compliance, without imputation for missing data. We also did several additional analyses. We did a per-protocol analysis, comparing participants who actually received surgery and those who actually received personalised hip therapy. Additionally, we compared participants randomly allocated to hip arthroscopy or personalised hip therapy, who received an allocated treatment that was deemed to be of high fidelity. We did prespecified subgroup analyses for different impingement types (cam, pincer, and mixed) and for patients younger and older than 40 years. We added pairwise interaction terms between treatment group and both impingement type and age group to the mixed-effects model to test for important subgroup effects. In addition to the primary adjusted analysis, we also reported unadjusted differences between groups, and we assessed significance using *t* tests for normally distributed outcomes. We present treatment effect estimates from the adjusted mixed-effects model (primary analysis) with 95% CIs. All hypothesis testing was at the 5% level, with no adjustments for multiple testing. Unless otherwise indicated, the analysis of secondary outcomes followed the same modelling approach as for the primary outcome. All analyses were on a complete-case basis and where follow-up data were missing, the reasons for missing data were obtained and patterns were investigated to judge the plausibility of missingness assumptions. We did a sensitivity analysis using multiple imputation techniques (imputation using chained equations) to assess the effect of missing data on the

	Hip arthroscopy (n=171)	Personalised hip therapy (n=177)
Age (years)	35·4 (9·7)	35·2 (9·4)
Sex		
Women	71 (42%)	64 (36%)
Men	100 (58%)	113 (64%)
Current smoker		
Yes	31 (18%)	25 (14%)
No	136 (80%)	151 (85%)
Missing data	4 (2%)	1 (1%)
Hip side considered for treatment		
Right	95 (56%)	103 (58%)
Left	75 (44%)	74 (42%)
Participants with bilateral symptoms	11 (6%)	18 (10%)
Duration of hip symptoms (months)	37 (36·6)	40 (40·8)
Impingement type		
Cam	129 (75%)	133 (75%)
Mixed	29 (17%)	30 (17%)
Pincer	13 (8%)	14 (8%)
Units of alcohol in an average week	6·2 (8·6)	6·0 (7·7)
Diabetes		
Yes	2 (1%)	4 (2%)
No	165 (96%)	171 (97%)
Missing data	4 (2%)	2 (1%)
Chronic renal failure		
Yes	1 (1%)	0
No	166 (97%)	176 (99%)
Missing data	4 (2%)	1 (1%)
Physical activity (UCLA Activity Scale)	4·3 (2·5)	4·4 (2·5)
Hip-related quality of life (iHOT-33)	39·2 (20·9)	35·6 (18·2)
SF-12 PCS	44 (7·6)	44 (5·9)
SF-12 MCS	42 (7·1)	42 (7·3)
EQ-5D 3L/5L Index Score	0·576 (0·26)	0·557 (0·25)
EQ-5D 5L VAS	67 (20·2)	67 (18·7)
Mean lateral centre edge angle (°)	31 (5)	31 (5)
Number of participants with LCEA <25°	7 (4%)	6 (3%)
Number of participants with LCEA <20°	0	0
Mean alpha angle (°) measured on antero-posterior radiograph	61 (17)	64 (18)

Data are mean (SD) or n (%). UCLA=University of California Los Angeles. iHOT-33=International Hip Outcome Tool. SF-12=12-item Short Form Health Survey. PCS=physical component score. MCS=mental component score. VAS=visual analogue score. LCEA=lateral centre edge angle.

Table 1: Baseline characteristics of the study population

primary outcome. Finally, we did a post-hoc sensitivity analysis of the effect of variation in recovery time in the hip arthroscopy group. We compared post-intervention adverse events between groups using Fisher's exact test. We did all analyses using Stata (version 14).²⁴

We did an economic evaluation from the perspective of the NHS and personal social services.²⁵ We estimated economic costs associated with the delivery of the two interventions. Resource use questions completed by participants at each assessment point provided a profile of

For the statistical analysis plan see www.warwick.ac.uk/ukfashion

	Hip arthroscopy (n=171)		Personalised hip therapy (n=177)		Unadjusted difference	Adjusted difference (95% CI)	p value
	Mean (SD)	n	Mean (SD)	n			
iHOT-33							
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)	0.0093
EQ-5D-5L (utility)							
6 months	0.544 (0.26)	144	0.573 (0.23)	147	-0.029	-0.042 (-0.088 to 0.005)	0.081
12 months	0.615 (0.25)	152	0.578 (0.24)	147	0.037	0.020 (-0.027 to 0.067)	0.397
EQ-5D VAS							
6 months	67.8 (19.3)	145	70.3 (19.3)	145	-2.5	-2.1 (-5.7 to 1.4)	0.241
12 months	71.9 (20.7)	150	69.2 (19.4)	145	2.7	2.6 (-1.2 to 6.4)	0.180
SF-12 PCS							
6 months	43.4 (7.0)	146	44.2 (6.6)	142	-0.8	-0.7 (-2.1 to 0.7)	0.304
12 months	45.1 (6.3)	145	44.2 (6.4)	132	1.0	1.1 (-0.2 to 2.5)	0.099
SF-12 MCS							
6 months	42.1 (7.3)	146	42.1 (7.2)	142	-0.1	-0.1 (-1.5 to 1.3)	0.929
12 months	43.2 (7.1)	145	42.6 (6.9)	132	0.6	0.4 (-1.2 to 2.0)	0.589

iHOT-33=International Hip Outcome Tool. VAS=visual analogue score. PCS=physical component score. MCS=mental component score. *Primary outcome.

Table 2: Patient-reported outcome measures

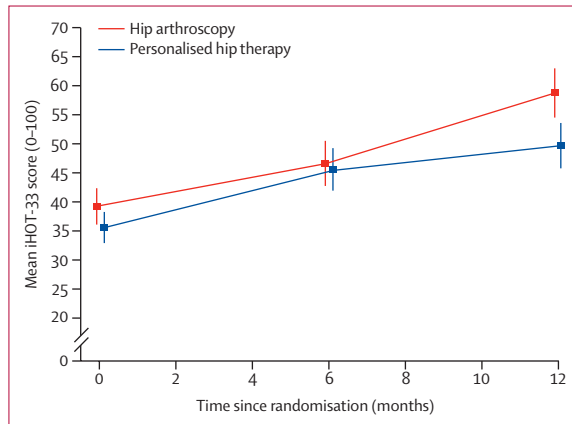


Figure 2: Changes in mean iHOT-33 score from baseline to 6 and 12 months after randomisation
Error bars are 95% CIs. iHOT-33=International Hip Outcome Tool.

all hospital inpatient and outpatient service use, community health and social care encounters, prescribed medications, and NHS supplies, such as crutches or home adaptations. We obtained unit costs (2016 £) from primary and secondary sources in accordance with national guidelines and attached them to every item of resource use.²⁴ We used health utilities generated from EQ-5D-5L responses at every timepoint of assessment to estimate quality-adjusted life-year (QALY) profiles for every participant; these QALYs were calculated as the area under the baseline-adjusted utility curve, assuming linear interpolation between utility measurements. We did a bivariate regression of costs and QALYs, with multiple

imputation of missing data, with the view to estimating the incremental cost per QALY gained for hip arthroscopy compared with personalised hip therapy. Further details, including sensitivity analyses done to assess the effect of uncertainty surrounding aspects of the economic evaluation, and prespecified subgroup analyses exploring heterogeneity in the cost-effectiveness results, are provided in the appendix. The trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN64081839.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between July 20, 2012, and July 15, 2016, 648 patients who attended the participating surgeons' hip clinics were deemed eligible (figure 1). Of these patients, 348 (54%) agreed to participate. The mean age of participants was 35.3 years (SD 9.6); the mean age of those who declined to participate was 35.4 years (10.3). The 348 participants were randomly allocated to receive hip arthroscopy (n=171) or personalised hip therapy (n=177). Three additional patients were randomly allocated in error, in each instance contrary to protocol procedures. One participant, who was not eligible, was recruited after miscommunication between the treating surgeon and recruiter; one patient was allocated without signing the consent form; and one patient was deemed eligible by a trainee surgeon, but within a few days the treating surgeon deemed they were not eligible. None of these patients participated in the trial (figure 1).

Participants in the two groups were well matched in terms of demographics and pre-randomisation hip-related quality of life, having had symptoms for approximately 3 years (table 1). 14 (8%) participants who were allocated to personalised hip therapy 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 personalised hip therapy. For hip arthroscopy, the median time from random assignment to treatment was 122 days (IQR 80–185), and for personalised hip therapy, it was 37 days (22–60). Surgeons did a mean of 112 (SD 55) hip arthroscopies per year during the study. At 12 months after randomisation, 144 (84%) of the 171 participants allocated to receive hip arthroscopy had received it; 27 (16%) had not. 121 (84%) participants who received a hip arthroscopy procedure had postoperative MRI and their case was assessed by the surgical review panel; 105 (87%) of these 121 procedures were deemed to be of high fidelity, and 16 (13%) were deemed unsatisfactory. The reasons for unsatisfactory surgery

	Hip arthroscopy (n=138)*	Personalised hip therapy (n=146)†	p value
Muscle soreness at 6 weeks after intervention	58 (42%)	69 (47%)	0.40
Numbness in groin, leg, or foot	35 (25%)	NA	NA
Hip pain or stiffness at 6 weeks after intervention	13 (9%)	8 (6%)	0.26
Unscheduled hospital appointments	13 (9%)	6 (4%)	0.096
Superficial wound problems	9‡ (7%)	NA	NA
Hip joint infection	1 (1%)	NA	NA
Fracture	0	NA	NA
Deep-vein thrombosis	0	NA	NA
Other adverse events potentially related to intervention	8 (6%; 2 numbness proximal thigh, 1 scrotal infection, 1 scrotal bruising, 1 labial swelling, 1 ankle pain, 1 erratic International Normalised Ratio, 1 nausea secondary to analgesia, 1 numbness to tip of tongue for 2 weeks after operation)	1 (1%; muscle spasms)	0.017
Other adverse events not related to intervention	10 (7%; 3 knee pain, 2 lower back pain, 1 shingles, 1 urinary tract infection, 1 essential thrombocythaemia, 1 hernia surgery, 1 contralateral foot pain)	18 (13%; 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 discoloration, 1 multiple sclerosis)	0.17

NA=not applicable. *Six of 144 patients who received hip arthroscopy within 12 months did not return an adverse events form. †Eight of 154 patients who received personalised hip therapy only did not return an adverse events form. ‡Four patients required antibiotics.

Table 3: Patient-reported adverse events

were an inadequate bony resection of the proximal femur (n=7) and acetabular rim (n=2), a sharp transition from the femoral head to neck as a result of reshaping surgery (n=5), and no reshaping surgery being done because the hip was degenerate (n=2). Nine (5%) of the 177 participants allocated to personalised hip therapy did not receive any treatment by 12 months. Of the patients who received personalised hip therapy (n=154), 107 (70%) were judged to have received the intervention to a high fidelity (appendix). The most common reason for low fidelity of personalised hip therapy was participants not receiving the minimum of six therapy sessions (34 [72%] of 47). Other reasons for low-fidelity personalised hip therapy were no progression of exercises by the physiotherapist (11 [23%] of 47) and the patient not complying with the exercise programme (two [4%] of 47).

319 (92%) of 348 participants completed the iHOT-33 questionnaires at 12 months after randomisation. Seven (2%) withdrew from follow-up, and 22 (6%) were lost to follow-up. The iHOT-33 score increased in both groups, indicating an improvement in hip-related quality of life (table 2, figure 2). 12 months after randomisation, mean iHOT-33 scores had improved from 39.2 (SD 21) to 58.8 (27) for participants in the hip arthroscopy group, and from 35.6 (18) to 49.7 (25) in the personalised hip therapy 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, p=0.0093) in favour of hip arthroscopy, compared with personalised hip therapy. In the per-protocol analysis at 12 months, including participants who received personalised hip therapy (n=154) or hip arthroscopy (n=144), the adjusted estimate of the between-group difference on iHOT-33 was 8.2 (95% CI 2.8 to 13.6) in favour of hip arthroscopy. In the

exploratory, pre-specified secondary analysis based on those participants whose treatment was deemed of a high fidelity (hip arthroscopy n=105, personalised hip therapy n=107), the adjusted estimate of between-group difference on the iHOT-33 was 5.8 (95% CI -0.7 to 12.2) in favour of hip arthroscopy. There were no significant between-group differences in SF-12 or EQ-5D-5L scores at 6 or 12 months after randomisation (table 2).

In the prespecified subgroup analyses, the between-group difference for iHOT-33 was 5.0 (95% CI -1.2 to 11.3) in participants younger than 40 years and 10.9 (1.7 to 20.1) in those older than 40 years ($p_{\text{interaction}}=0.3023$) in favour of hip arthroscopy; the difference was 8.3 (95% CI 2.5 to 14.2) in patients with cam morphology, 1.1 (-11.5 to 13.7) in those with mixed cam and pincer morphology, and 4.0 (-14.6 to 22.7) in those with pincer morphology ($p_{\text{interaction}}=0.5672$), in favour of hip arthroscopy.

Among patients who received their allocated intervention, there were 147 patient-reported adverse events (in 100 [73%] of 138 patients) in the hip arthroscopy group versus 102 (in 88 [60%]) of 146 patients in the personalised hip therapy group. The most frequently reported adverse event was muscle soreness, reported by 58 (42%) patients in the hip arthroscopy group and 69 (47%) patients in the personalised hip therapy group (table 3). At 12 months, seven serious adverse events had been reported by participating hospitals. Six of these were among the participants in the hip arthroscopy group: one patient was not discharged from the day surgery unit and required an overnight admission, one patient had scrotal haematoma requiring readmission, two patients had superficial wound infections that required oral antibiotics, one patient had a hip joint infection that required further surgery and ultimately a

total hip replacement, and one patient had a fall that was unrelated to hip arthroscopy. One participant in the personalised hip therapy group developed biliary sepsis that was unrelated to treatment. There were no treatment-related deaths.

There was a low level of missing item-level data (eg, iHOT-33 0.6%) in all patient-reported outcome measures at all timepoints; 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. In a post-hoc analysis there was no significant difference in iHOT-33 at 12 months for patients in the hip arthroscopy group who were treated within 6 months of randomisation versus those treated 6 months or more after randomisation (0.9 [95% CI -10.7 to 8.8]). We assessed model assumptions, including assessment of quantile-quantile plots, which were deemed adequate. 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 personalised hip therapy group attended a mean of six physiotherapy sessions (average duration of 30 min), generating mean total treatment costs of £155 per participant. The adjusted incremental cost of hip arthroscopy compared with personalised hip therapy during the 12-month follow-up was £2372, with incremental QALYs of -0.015 (representing a net QALY loss). Personalised hip therapy was more cost-effective than hip arthroscopy at 12 months (appendix).

Discussion

The UK FASHIoN study is the first randomised controlled trial to provide evidence that hip arthroscopy is effective in patients with femoroacetabular impingement syndrome. In this pragmatic trial, we found that iHOT-33 scores improved for patients in both groups; 12 months after randomisation, there was a mean adjusted difference of 6.8 points in the iHOT-33 score between patients allocated to receive hip arthroscopy and those allocated to receive personalised hip therapy, in favour of hip arthroscopy. This is a statistically significant difference that also exceeded the minimum clinically important difference for iHOT-33. These 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 are at high risk of bias.⁶ Results from a Cochrane systematic review done by members of our group¹¹ showed that there had been no previous relevant randomised controlled trials. Since then, one recent randomised controlled trial²⁶ has reported no difference between hip arthroscopy and conservative care. This study was small, was done 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.²⁶ When the authors did 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”.²⁶ They concluded that “large cohorts across multiple sites are needed to make definitive conclusions”.²⁶ Our trial is larger and therefore has greater power to detect between-group differences, and was done in 23 centres with a more generalisable patient population.

There were no differences between groups in the secondary outcome measure of general health-related quality of life (EQ-5D-5L and SF-12). This finding could either be because treatment for femoroacetabular impingement syndrome does not have an effect on health-related quality of life or because the measures we used 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.

Adverse events in the hip arthroscopy group were more frequent than in the personalised hip therapy group. However, there was only one serious surgical complication in which a patient developed a hip joint infection. In one systematic review of 36761 cases,²⁷ hip arthroscopy had a reported complication rate of 3.3%, with a rate of major complications of 0.2%; our study findings are consistent with this.

Our within-trial health economic evaluation suggests that hip arthroscopy is not cost-effective by comparison with personalised hip therapy. However, our economic models were only able to assess cost-effectiveness at 12 months from randomisation. This finding must also be set in the context of the high initial treatment costs of hip arthroscopy, the treatment timing (long delay in patients receiving hip arthroscopy, reducing the period of potential benefit during follow-up), and the period of economic inactivity during postoperative recovery (appendix). There could be long-term benefits from treatment that were not assessed in this economic analysis. We plan further follow-up points at 2, 3, 5, and 10 years, which will inform the lifetime cost-effectiveness of both surgery and personalised hip therapy, and whether treatment effects are maintained or if further treatments are required. Comparison of the rates of hip replacement in both groups will also help establish whether surgery affects the risk of osteoarthritis.¹³

Strengths of this trial include the consent to participate rate among eligible patients (54%) and the follow-up rate (92%). Both of these values are high compared with similar trials in orthopaedics, and especially with trials of surgery versus no surgery, contributing to external and internal validity.²⁸ The integrated qualitative research optimised recruitment, as it has done in other trials.¹⁵ This trial was thoroughly pragmatic, exploring the effectiveness of a strategy of offering hip arthroscopy compared with conservative care in the everyday reality of a national health service, where patients do 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 is a strength, which contributes to the generalisability of our findings. The comparator for this trial was personalised hip therapy, which we consider to be the best conservative care that can realistically be provided in the NHS for these patients. Personalised hip therapy was designed through international consensus and developed, supported, and tested in similar ways to other physiotherapist-led conservative care protocols.²⁹ It meets the standards expected of a complex intervention in a randomised controlled trial, and was delivered by musculoskeletal physiotherapists who attended additional training and support events.^{6,7,30}

Limitations of this trial include that participants and treating clinicians were not masked to treatment allocation. A blinded allocation trial, with a placebo control, would have been better suited to measuring the underlying effect of surgery. In our trial, the research question was whether hip arthroscopy or best conservative care was the most effective treatment strategy, leading to an inevitable absence of blinding. Data collection and analysis were done without revealing treatment allocation. An unexpected difficulty was the frequent delay in delivery of surgery for those patients allocated to hip arthroscopy. We had anticipated that this delay would be less than 3 months in most patients because when we designed the trial, there was a strongly enforced NHS target to treat patients within 18 weeks from referral to surgery. In fact, during the study, this target was a challenge in many hospitals. Patients allocated to hip arthroscopy therefore often had longer times to treatment, and because the primary outcome was measured 12 months after randomisation, these patients were often still within a few months (and in some cases a few weeks) of their operation when we measured the primary outcome. Because of these delays, patients in the hip arthroscopy group had, on average, less time to recover before the primary outcome measurement than did patients in the personalised hip therapy group. We compared 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. There was no significant difference between these groups, suggesting that the systematic difference in time to treatment between groups does not account for the treatment effect. Our inferences about the effectiveness of hip arthroscopy compared with personalised hip therapy are limited to data collected 12 months after randomisation; long-term follow-up is required to establish if this effect is maintained and if further treatments are required.

The fact that not all surgery or personalised hip therapy was deemed to be of a high fidelity is also a reflection of the real-world setting in which this trial was done. Some surgery was not satisfactory, and some participants

allocated to personalised hip therapy did not engage with it or complete it: our fidelity assessment showed high-fidelity treatment in 87% of patients receiving hip arthroscopy and 70% of patients receiving personalised hip therapy. However, these proportions are comparable with other studies and reflect the pragmatism of our trial.³¹ We took great effort to minimise crossover in our trial, using techniques developed in our feasibility study. No participants allocated to receive hip arthroscopy received personalised hip therapy; 14 participants allocated to personalised hip therapy subsequently changed their mind and decided to have surgery within 12 months. We do not believe that these crossovers can account for the results of this trial; indeed, we would expect such crossovers to dilute and so reduce our estimate of the real underlying effect of hip arthroscopy.

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 our 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 results of our subgroup analysis of patients with only cam morphology are suggestive of an increased treatment effect of hip arthroscopy compared with other shapes. This finding would support the idea that the removal of a cam shape has a specific therapeutic effect. The low number of patients with pincer or mixed cam and pincer morphology in this study means we are less certain about the influence of reshaping the acetabular rim. Ultimately, we do not fully understand the mechanism of benefit from hip arthroscopy or personalised hip therapy. Future research should focus on investigating these mechanisms further, and which patients would benefit most from hip arthroscopy or personalised hip therapy.

We have shown that offering hip arthroscopy to patients with femoroacetabular impingement syndrome led to better patient-assessed function 12 months after randomisation, compared with best conservative care. This improvement comes at a cost; our study does not show cost-effectiveness of hip arthroscopy compared with conservative care within the first 12 months.

Contributors

DRG, PDHW, RH, NEF, CEH, JLD, AR, and SP did the feasibility and pilot trial and wrote the grant application for this trial. DRG was the chief investigator. NEF and PDHW led development of personalised hip therapy intervention, and NEF, JS, and EJD supported participating physiotherapists in its delivery. EJD and RH were responsible for administrative set-up and performance of the trial, and centre staff training. CEH and EJD were responsible for collating and analysing the radiological data. NRP and JG provided statistical input to design, performance, and analysis of the trial. SP and FA designed and did the health economic analysis. AR, MJ, and JLD did the qualitative research recruitment intervention. DRG, JG, and NRP had access to all study

data. DRG drafted the final report; all of the FASHIoN investigators have been involved in revising the report, and all of the authors have seen and approved the final version. DRG is the guarantor for this study and decided to submit the manuscript.

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Declaration of interests

DRG reports grants from the National Institute of Health Research (NIHR) during the conduct of the study, and personal fees from Stryker UK, outside the submitted work; he is also a board member of the International Society of Hip Arthroscopy, and is a consultant surgeon who routinely performs hip arthroscopy. PDHW, MJ, JLD, CEH, NRP, and NEF report grants from the NIHR Health Technology Assessment Programme during the conduct of this study. All other authors declare no competing interests.

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