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Protocol for a multi-centre, parallel-arm, 12-month, randomised controlled trial of arthroscopic surgery versus conservative care for femoroacetabular impingement syndrome (FASHIoN).

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Abstract

Introduction

Femoroacetabular impingement (FAI) syndrome is a recognised cause of young adult hip pain. There has been a large increase in the number of patients undergoing arthroscopic surgery for FAI, however a recent Cochrane review highlighted that there are no randomised controlled trials evaluating treatment effectiveness.

We aim to compare the clinical and cost effectiveness of arthroscopic surgery versus best conservative care for patients with symptoms of FAI syndrome.

Methods,

We will conduct a multi-centre, pragmatic, assessor blinded, two parallel arm, randomised controlled trial comparing arthroscopic surgery to physiotherapy led best conservative care. Twenty-four hospitals treating NHS patients will recruit 344 patients over a 26-month recruitment period. Symptomatic adults with radiographic signs of FAI morphology who are considered suitable for arthroscopic surgery by their surgeon will be eligible. Patients will be excluded if they have radiographic evidence of osteoarthritis, previous significant hip pathology or previous shape changing surgery. Participants will be allocated in a ratio of 1:1 to receive arthroscopic surgery or conservative care. Recruitment will be monitored and supported by qualitative intervention to optimise informed consent and recruitment.

The primary outcome will be pain and function assessed by the international hip outcome tool 33 (iHOT-33) measured 1 year following randomisation. Secondary outcomes include general health (short form 12), quality of life (EQ5D-5L) and patient satisfaction. The primary analysis will compare change in pain and function (iHOT-33) at 12 months between the treatment groups, on an intention-to-treat basis, presented as the mean difference between the trial groups with 95% confidence intervals.

The study is funded by the Health Technology Assessment Programme (13/103/02).

Ethics and Dissemination:

Ethical approval is granted by the Edgbaston Research Ethics committee (14/WM/0124). The results will be disseminated through open access peer-reviewed publications, including *Health Technology Assessment*, and presented at relevant conferences.

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Trial Registration:

ISRCTN64081839

Strengths and Limitations

- This trial is multi-centre, pragmatic and randomised making results generalisable across the NHS.
- Further strengths include a large sample size and the robust procedures to assess treatment fidelity.

Background

Until recently, there was little understanding of the causes of hip pain in young adults. Since first described in 2003 there has been increasing recognition of the syndrome of femoroacetabular impingement (FAI), which seems to account for a proportion of the previously undiagnosed cases of hip pain in young adults.[1 2] Subtle deformities of hip shape combine to cause premature contact between the femoral neck and the acetabular rim which may result in hip pain.[1 3] These shape abnormalities typically divide into three categories:[3 4]

- Cam-type, in which the femoral head is oval rather than round, or there is bony prominence on the femoral neck;
- Pincer-type, in which the rim of the acetabulum is excessively prominent, in one or more areas of its circumference;
- Mixed-type hip impingement, a combination of cam and pincer types.

Surgery can be performed to reshape the bony contour of the proximal femur and/or acetabular rim in order to prevent impingement. Surgery for FAI has evolved more quickly than our understanding of the epidemiology or natural history of the condition,[5 6] and is becoming an established treatment for FAI.[7] The risks of complications from open surgery are greater than those for arthroscopic surgery and current evidence suggests that the outcomes of arthroscopic treatment for the symptoms of FAI are comparable to open surgery.[8],[9] Consequently, hip arthroscopy for FAI is a rapidly growing new cost pressure for health providers.[10] However a recently published Cochrane review highlighted the absence of randomised controlled trials comparing FAI surgery with conservative care such as physiotherapist-led exercise.[11] Physiotherapy has also been shown to be beneficial in patients with FAI syndrome.[12],[13] During a successful feasibility study (HTA 10/41/02) a programme of physiotherapist-led conservative care was developed called personalised hip therapy (PHT).[14]

Aims of Trial

We aim to compare the clinical and cost effectiveness of arthroscopic surgery versus physiotherapist-led conservative care (PHT) in patients with symptoms of FAI syndrome.

Methods/ Design

This trial will be conducted in accordance with the Medical Research Council's Good Clinical Practice principles and guidelines, the Declaration of Helsinki, Warwick Clinical Trials Unit (WCTU) standard operating procedures (SOPs), relevant UK legislation and the trial protocol. Ethical approval was granted on 1/5/2014 (14/WM/0124), by the Edgbaston Research Ethics committee (current approved protocol version 3.1 20/01/2016). The trial will be reported in line with the CONSORT statement. This full trial follows a successful feasibility and pilot trial (HTA10/41/02).[14]

Trial Design and Setting

This is a protocol for the **f**ull UK randomised controlled trial of **a**rthroscopic **s**urgery for **h**ip **i**mpingement versus best c**on**servative care (**FASHIoN**). We will conduct a multi-centre, pragmatic, assessor blinded, parallel arm, 12-months, 1:1 randomised controlled trial of hip arthroscopy versus conservative care for FAI assessing patient pain, function, general health, quality of life, satisfaction and cost effectiveness. There is an integrated qualitative recruitment intervention (QRI) that includes interviews with recruiters and patients, and observations of recruitment appointments to ensure patients have the opportunity to fully consider participation in the trial.[15]

We hypothesise that arthroscopic surgery is superior to conservative care at 12 months for self reported hip pain and function for patients with FAI syndrome.

The trial will be conducted in private and NHS hospitals with their linked physiotherapy services, treating NHS patients in the UK. Hospitals participating

in FASHIoN will have an organised hip arthroscopy service treating at least 20 patients with arthroscopic surgery for FAI per year.

Target Population

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

Inclusion criteria

- Age ≥16 (no upper age limit);
- Symptoms of hip pain - patients may also have symptoms of clicking, catching or giving way;
- Radiographic evidence of pincer- and/or cam-type FAI morphology on plain radiographs and cross-sectional imaging, defined as:
    - Cam morphology - an alpha angle >55º [16]
    - Pincer morphology - a lateral centre edge angle of >40º or a crossover sign on the anteroposterior radiograph of the pelvis [17]
- The treating surgeon believes the patient would benefit from arthroscopic FAI surgery;
- The patient is able to give written informed consent and to participate fully in the interventions and follow-up procedures.

Exclusion criteria

- Evidence of pre-existing osteoarthritis, defined as Tonnis grade >1, [18] or more than 2mm loss of superior joint space width on anterio-posterior pelvic radiograph;[19]
- Previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis, or avascular necrosis;
- Previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture;

- Previous shape changing surgery (open or arthroscopic) in the hip being considered for treatment.

Participant identification, invitation, recruitment and baseline data collection

Patients who complain of hip pain, who do not already have a diagnosis of hip osteoarthritis, will be identified as potential participants by screening referral letters to collaborating surgeons. Research nurses/associates will keep accurate screening logs to identify if these potential participants meet the eligibility criteria. Once diagnosed with FAI, and deemed eligible for the trial, the patient will be given a trial information sheet (see supplementary document) and be invited to attend a trial information consultation with a trained recruiter. During this consultation patients can discuss the trial, participation will be offered, and informed consent obtained (see supplementary document). It will be explained that participation is voluntary and patients can withdraw at any time. Once consent is obtained, and prior to treatment allocation, baseline patient reported outcomes will be collected (see outcome measures below).

In order to optimise recruitment and informed consent trained qualitative researchers will observe recordings of the surgeons' and research associate/nurses' trial information consultations (see supplementary documents), to identify communication patterns that facilitate or hinder patient recruitment.[15] See Figure 1 – Flow Diagram. In-depth interview with the recruiters will be undertaken to identify clear obstacles and hidden challenges to recruitment, including the influence of patient preferences and equipoise.[20] Research teams will be interviewed to identify clinician equipoise, patient pathway from eligibility to consent, and staff training needs at each participating site.[15] Findings will be fed back to the CI and trial management group (TMG) so that practice can be reviewed and any necessary changes (including additional training) implemented. The number of eligible patients, the percentages of these that are

approached and consented to be randomised will be monitored at each site. This research will be linked, through Donovan, to the Quintet programme of research within the MRC ConDuCT-II (Bristol) Trial Methodology Hub.

<insert figure 1 "Figure 1 Participant Flow Diagram">

Randomisation

Participants will be randomised, in a 1:1 ratio, to arthroscopic surgery or PHT using a computer generated sequence. Allocation will be made by the research nurse/associate via a centralised telephone randomisation service provided by WCTU. Allocation concealment will be ensured, as the randomisation programme will not release the randomisation code until the patient has been recruited into the trial. In order to improve baseline balance between intervention group samples, a minimisation (adaptive stratified sampling) algorithm will be implemented using study site and impingement type (cam, pincer or mixed) factors. Research nurses/ associates who recruit participants will ensure they are referred for the allocated intervention. Outcome assessors, including trial statisticians, will be blind to the treatment delivered, however this will not be possible for participants or treating clinicians. However treating clinicians will not be involved in outcome assessment.

Interventions

The two interventions will commence as soon as possible after randomisation. We will record dates of randomisation and the start of allocated treatment. As this is a pragmatic trial subjects were not prohibited from undergoing any concomitant care.

Arthroscopic Surgery

Arthroscopic surgery will be completed by a Consultant Surgeon delivering hip arthroscopy as part of their routine practice. Arthroscopic hip surgery will be

performed under general anaesthesia according to the surgeon's usual practice. Shape abnormalities and consequent labral and cartilage pathology will be treated. Bony resection at the acetabular rim and at the head-neck junction will be assessed by intraoperative image intensifier radiographs and/or satisfactory impingement free range of movement of the hip. Patients will be allowed home when they can walk safely with crutches (usually within 24 hours). On discharge patients will be referred for a course of rehabilitation as per usual care for that surgeon. We will not specify a protocol for this post-operative physiotherapy, but will record the surgeons' routine post op care and any case-by-case changes to this. Care will be taken to ensure that physiotherapists delivering post-operative care to FASHIoN trial participants are different from those trained and providing PHT in order to avoid contamination between groups. Patients will also have a post-operative MRI after 6 weeks.

In order to ensure the fidelity of the surgery and to identify participants for a secondary analysis, a panel of international experts will review operation notes, intra operative images and post-operative MRI scans to assess whether adequate surgery was undertaken. This panel includes: Mark Philippon (USA), Martin Beck (Switzerland), John O'Donnell (Australia) and Professor Charles Hutchinson (UK).

Personalised Hip Therapy (PHT)

PHT is a package of physiotherapist-led best conservative care for FAI. It was developed during the feasibility study and 'road-tested' during the pilot trial (HTA 10/41/02). The care being offered represents a consensus of what physiotherapists, physicians and surgeons regard as 'best conservative care' for FAI. PHT will be delivered by a senior physiotherapist at each site, who will be trained at a FASHIoN PHT workshop, and supported in PHT delivery by a physiotherapy research facilitator.

PHT consists of four key components:

1) An assessment of pain, function and range of hip motion,

2) Patient education and advice
3) Help with pain relief (which may include up to one radiographic guided intra-articular steroid injection where pain prevents performance of the exercise programme)
4) An exercise programme that has the key features of individualisation, progression and supervision.

The intervention is delivered over a minimum of 6 patient contacts (at least 3 of which must be face-to-face treatment contacts, others can be by telephone and email) over a period of 6 months. In situations where the patient needs additional review, support or guidance, further sessions with the physiotherapist are permitted. Evidence of exercise individualisation, supervision and progression will be sought from individual participant physiotherapy case report forms (CRFs). Accuracy of CRFs will be audited against the physiotherapist's treatment notes.

The PHT CRFs will be assessed for intervention fidelity to identify participants for a secondary analysis by the panel that developed the protocol for PHT including: Professor Nadine Foster (Senior Academic Research Physiotherapist), Ivor Hughes and David Robinson (UK; Extended Scope Musculoskeletal Physiotherapists) and Peter Wall (Academic Orthopaedic Surgeon).

Cross-over of participants between interventions can be problematic in trials of this nature. In order to minimise this care will be taken prior to enrollment in the trial to ensure potential participants:

- Are willing to receive either intervention.
- Understand both treatments are thought to provide benefit
- Are willing to remain with their allocation for 12 months.
- Understand that both interventions may take 6 months to improve symptoms.[12 19]

In instances where patients are not satisfied with how their treatment is progressing prior to reaching the primary outcome they will be able to have a

further consultation with their treating surgeon where they would be treated in their best interests.

Risks and benefits

Both interventions are thought to provide benefit in patients with FAI. The short-term risks of this study relate to the two interventions. These risks are described below and inform the expected serious adverse events (SAEs):

Hip arthroscopy requires a general anaesthetic. The risk of complications from hip arthroscopy is about 1-2%[45]. These include:

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

PHT

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

Outcome Measures

Baseline data will be collected from participants once consent is obtained and prior to randomisation. Follow up questionnaires will be administered centrally by a data clerk via post. If participants fail to respond they will be contacted via

telephone, email or via their next of kin where necessary. Table 1 lists the data collected and at which follow up time points.

Primary Outcome

The primary outcome measure is hip pain, function and hip related quality of life using the **International Hip Outcome Tool-33** (iHOT-33) at 12 months following randomisation. iHOT-33 is a validated hip specific patient-reported outcome tool which measures health-related quality of life in young, active patients with hip disorders[21]. It consists of the following domains: symptoms and functional limitations, sports and recreational activities, job related concerns and social, emotional and lifestyle concerns.

We chose it following our feasibility and pilot study as:

- It is more sensitive to change than other hip outcome tools,[21]
- It does not show evidence of floor or ceiling effects in patients undergoing hip arthroscopy,[21]
- Patients were involved extensively in item generation; so we can be confident that it measures what is most important to patients,[21]
- There is an independently determined minimally clinically important difference (MCID),[21]
- It is used as the principal outcome measure for the UK Non-Arthritic Hip Registry; mandated for arthroscopic FAI surgery by the National Institute of Health and Clinical Excellence (NICE).[10]

Secondary Outcome Measures

Health related quality of life: **EQ-5D 5L**. This is a validated measure of health-related quality of life, consisting of a five dimension health status classification system and a separate visual analogue scale. EQ-5D is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status.[22] Responses will be converted into health utility scores using established algorithms.[23]

General health: **Short Form-12 Health Survey V2**. This is a validated and widely-used health-related quality of life measure particularly including hip conditions and treatments.[24] SF-12 is able to produce the physical and mental component scales originally developed from the SF- 36 with considerable accuracy but with far less respondent burden.[25] Responses will be converted into health utility scores using established algorithms.[26]

Patient satisfaction using questions that our team (Foster) has used in previous trials with musculoskeletal pain patients,[27] we will measure two distinct dimensions of satisfaction in all participants during follow-up: '*Overall, how satisfied are you with the treatment you received?'* and *'Overall*, *how satisfied are you with the results of your treatment?'* Responses are on a 5-point Likert scale. These questions are in line with previous studies of patient satisfaction which show that the majority of patients express overall satisfaction with the care they received, but fewer express overall satisfaction with the clinical outcomes resulting from their care.

Qualitative assessment of outcome; we will conduct in-depth interviews with a purposively selected sample of 25-30 participants in each of the trial groups, including older and younger, male and female, more and less active, and more and less satisfied participants recruited at different trial sites. The qualitative interviews will supplement the quantitative outcomes. Interviews will explore experiences of the trial processes, the treatments, and the consequences of treatment to participants' lives, health and wellbeing.

Adverse Events We will record number and type of adverse events (AEs) up to 12 months. Any AEs will be reported on the appropriate CRF and returned to WCTU. Any SAEs will be faxed to WCTU, within 24hours of the local investigator becoming aware, where the Chief Investigator will determine causality and expectedness. SAEs deemed unexpected and related to the trial will be reported to the research ethics committee within 15days.

Resource utilisation Information on health care resource use will be collected by incorporating questions within the patient follow-up questionnaires. We confirmed the feasibility and acceptability of this approach in our pilot trial, and patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.[28]

Need for further procedures We will record any further treatments performed in both groups, such as hip arthroscopy, open hip preservation surgery, hip replacement, or additional "out of trial" physiotherapy. We propose to ascertain the need for further procedures by questionnaire at two and three years. We also propose a 5 and 10-year no-cost ascertainment of hip replacement by linkage to the UK National Joint Registry (NJR) and Hospital Episode Statistic (HES) databases.

Table 1 Data Collection Time points

Time point	Data collection
Baseline	Demographics, physical activity (UCLA Activity Scale),[29] iHOT-33, SF-12,EQ-5D Preoperative imaging, economics questionnaire.
Intervention	Operation notes and photographs; or PHT log. Complications records 6 weeks post start of intervention. Post-op MRI (surgery intervention only)
6 months	iHOT-33, SF-12, EQ-5D, resource utilisation, adverse events
12 months (primary outcome)	iHOT-33, SF-12, EQ-5D, patient satisfaction, resource utilisation, adverse events
2 years	Further procedures questionnaire
3 years	Further procedures questionnaire
5 & 10 years	Linkage to National Joint Registry and HES to identify need for hip replacement

Sample Size Calculation

The development work for iHOT-33 reported a mean iHOT-33 score of 66 and a standard deviation of 19.3 in a heterogeneous population with a variety of hip

pathologies. The baseline iHOT-33 data from our pilot trial (HTA grant 10/41/02) suggests the target population of patients being considered for hip arthroscopy for FAI have lower scores with less variability, with a mean of 33 and SD of 16. The MCID for iHOT-33 in this population is 6.1 points.[21]

Our sample size calculation is therefore based on a SD of 16 and a between group MCID of 6.1: a standardised effect difference between groups at 12 months of 0.38. The expected sample size for 90% power to detect an effect size of 0.38 at 12 months, at a 5% significance level, assuming an approximately normal distribution of the iHOT-33 score is 292. Allowing for 15% loss to follow-up at 12 months, we will recruit a sample of 344 participants over 26months in the UK (172 in each group).

Statistical Analysis

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

The minimisation randomisation procedure should ensure treatment group balance across recruiting sites. We have no reason to expect that clustering effects will be important for this study, but the possibility of such effects will be explored as part of the analysis.[33] We plan to account for clustering by generalising a conventional linear (fixed-effects) regression approach to a mixed-effects modelling approach; where patients are naturally grouped by recruiting sites (random-effects) and, if amenable to analysis, also by physiotherapist and surgeon. This model will formally incorporate terms that allow for possible heterogeneity in responses for patients due to the recruiting centre, in addition to the fixed effects of the treatment groups, and patient characteristics that may prove to be important moderators of treatment effect such as age, gender and FAI type. This analysis will be conducted using specialist mixed-effects modelling functions available in the software packages Stata (StataCorp. 2015. Stata

Statistical Software: Release 14. College Station, TX: StataCorp LP) and R (http://www.r-project.org/). All tests will be two-sided and considered to provide evidence for a statistically significant difference if p-values are less than 0.05 (5% significance level).

Secondary analyses will be performed using the above strategy for other approximately normally distributed outcome measures including iHOT-33 at 6 months, SF-12 (and computed sub-scales) and EQ5D. Differences in dichotomous outcome variables such as adverse events, complications related to the trial interventions and the need for further procedures will compared between groups using chi-squared tests (or Fisher's exact test) and mixed effects logistic regression analysis will be undertaken, adjusting for the stratifying variables, with differences between trial intervention groups quantified as odds ratios (and 95% confidence intervals). The temporal patterns of any adverse events will be presented graphically and if appropriate a time-to-event analysis (Kaplan-Meier survival analysis) will be used to assess the overall risk and risk within individual classes of adverse events. Ordinal scores for patient satisfaction will be compared between intervention groups using proportional odds logistic regression analysis, assuming that the estimated intervention effect between any pair of categories is equivalent.

Our inferences will be drawn from the intention to treat-analysis. We will perform two exploratory secondary analyses. One will compare patients who received surgery and those who received conservative care. A second exploratory analysis will compare patients randomised to surgery or PHT and received treatment deemed to be of a high fidelity by the respective review panels. We plan to perform a subgroup analysis by FAI type because it is possible that treatment effect is moderated by type. We anticipate that adequate steps have been taken to prevent crossovers from being a major issue for this study. Therefore we expect the main intention-to-treat analysis to provide definitive results. An independent Data Monitoring Committee (DMC) will monitor crossovers and adherence to treatment and advise on appropriate modifications to the statistical analysis plan as the full trial progresses.

The initial feasibility and pilot studies (HTA 10/41/02) were designed explicitly to assess feasibility and measure recruitment rates, and not to estimate treatment effectiveness. Data from the pilot will be pooled with data from the full trial, and analysed together.

Economic Analysis

An economic evaluation will be integrated into the trial design and will be conducted from the recommended NHS and personal social services perspective.[30] Cost-effectiveness will be calculated using both within trial and lifetime horizons. Data will be collected on the health and social service resources used in the treatment of each trial participant until 12 months.
An incremental cost-effectiveness analysis, expressed in terms of incremental cost per quality-adjusted life year gained, will be performed. Results will be presented using incremental cost-effectiveness ratios and cost-effectiveness acceptability curves generated via non-parametric bootstrapping.

Qualitative Interview Analysis

Participant interview transcripts will be analysed thematically, using methods of constant comparison derived from grounded theory.[31] Emerging themes will be explored, looking for shared or disparate views among patients about their experiences, and among clinicians about their experiences of delivering the trial interventions. Focused conversation analysis will be undertaken on sections of recruitment appointments, and compared with the six-step good recruitment model developed in the pilot study to identify aspects of RCT presentation that are unclear, disrupted or hinder recruitment.[15 20 32]

Data Management

All of the data collected in this trial will be entered into a secure trial database held at the Clinical Sciences Research Laboratories, University Hospitals Coventry and Warwickshire. All data collected will be anonymised after the

collection of baseline demographic data, and all participants given a unique trial number. Identifiable participant data will be held in a locked filing cabinet and coded with a trial participant number to tag identifiable data to the outcome data. The WCTU quality assurance manager will undertake audits of trial records in accordance with WCTU SOPs.

A DMC will be established comprised of members who are independent of the sponsor and who do not have competing interests. The DMC will review trial progress, interim data and safety aspects of the trial. They will also review the statistical analysis plan. Any recommendations will be fed back to the trial steering committee (TSC) by the DMC chair. Outcomes will not be analysed until all primary outcome data are collected. The trial may be stopped pre-maturely if mandated by the research ethics committee, the DMC or if funding ceases.

Discussion

This protocol paper describes the FASHIoN trial; a multicenter RCT comparing hip arthroscopy to best conservative care (PHT) in order to establish the most clinically and cost-effective treatment for patients with FAI syndrome. Further details of the trial protocol can be found on the ISRCTN registry (ISRCTN64081839). This protocol will also be used for a randomised trial in Australia (ACTRN12615001177549). The results of the trial will be disseminated at international meetings and in peer reviewed journals; to participants via post and to the public via the trial website.

The main strengths of this trial are that it is multi-center, pragmatic and randomised making results generalisable across the NHS. Further strengths include a large sample size and the robust procedures to assess treatment fidelity.

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The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing Interests:

The Chief Investigator and many of the co-investigators are Orthopaedic Surgeons who perform FAI surgery in the NHS and within private practice.

Ethics Approval: Ethical approval was granted on the 12th Febuary 2012 (11/WM0389) and on the 1st of May 2014 (14/WM/0124), by the Edgbaston Research Ethics committee.

Trial Sponsor: University of Warwick, Gibbett Hill Rd, Coventry, CV4 7AL

Acknowledgments:

FASHIoN Study Group; see supplementary file for full details.

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Contributorship: DG is the Chief Investigator of the FASHIoN Trial. DG led the conception, design, acquisition, analysis and interpretation of data. DG contributed to drafting and approved the final submitted version of this manuscript.

ED contributed to the design, acquisition, analysis and interpretation of the data. ED contributed to the drafting and approved the manuscript.

PW contributed to the conception, design and acquisition of the trial data. PW contributed to drafting the manuscript and approved the final version

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NP contributed to the conception, design, analysis and interpretation of the data. NP contributed to the drafting and approved the manuscript.

SP contributed to the conception, design and interpretation of the data for the trial. SP contributed to the drafting and approved the manuscript.

AR contributed to the acquisition, analysis and interpretation of the trial data. AR contributed to the drafting and approved the manuscript.

JA contributed to the conception, design and analysis of the trial data. JA contributed to the drafting and approved the manuscript.

FA contributed to the analysis and interpretation of the trial data. FA contributed to the drafting and approved the manuscript.

AA contributed to the conception and design of the trial. AA contributed to the drafting and approved the manuscript.

MC contributed to the conception and design of the trial. MC contributed to the drafting and approved the manuscript.

JG contributed to the acquisition, analysis and interpretation of trial dat. JG contributed to the drafting and approved the manuscript.

RH contributed to the conception, design and acquisition of the trial data. RH contributed to the drafting and approved the manuscript.
JS contributed to the acquisition, analysis and interpretation of the trial data. JS contributed to the drafting and approved the manuscript.

Data Sharing: It is our intention to publish the results of the trial in peer reviewed journals and presented at international meetings. It is not our intention to withhold any data from publication.

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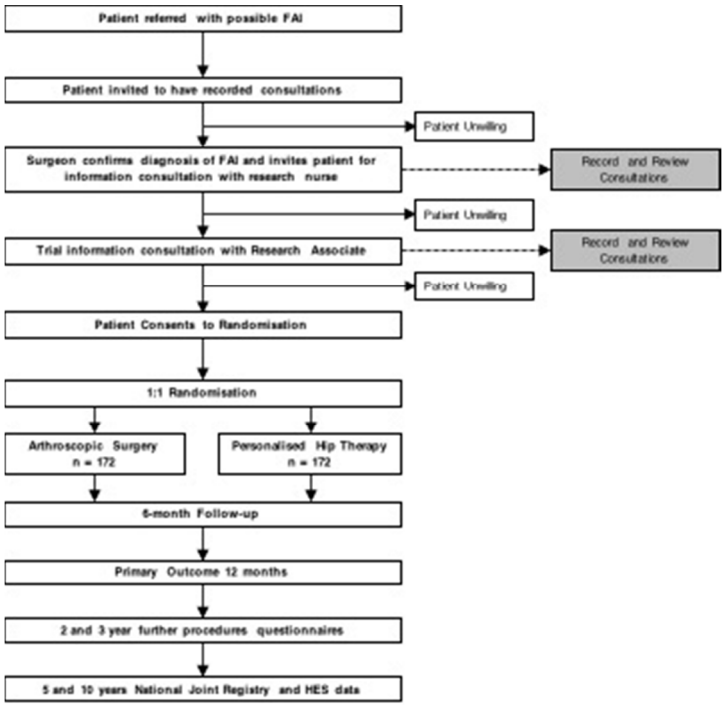


Figure 1 Participant Flow Diagram
126x123mm (72 x 72 DPI)

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

UK FASHIoN Study

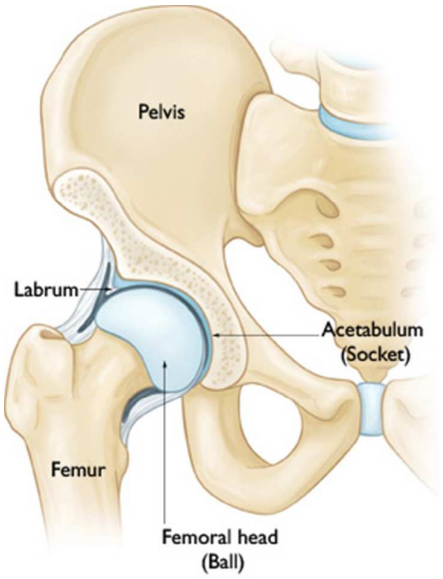
Chief Investigator: Professor Damian Griffin

Patient Information Sheet

You are invited to take part in our research study. Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. Once you have had a chance to read and absorb this information sheet a member of our team will personally go through the information with you and answer any questions you may have.

Background Information

Your hip joint has two bones that fit together like a ball in a socket, see figure 1.



- Figure 1 – Normal Hip Joint

The bones that make the ball and socket joint are not the same shape in everyone. In some people with a shape similar to yours the bones press against each other and damage the local soft tissues such as the labrum (a soft cushioning around the hip joint- see figure 1) which can cause pain.

This is called Hip Impingement and the medical term for this is femoroacetabular impingement (FAI for short). Hip impingement has only been discovered in the last 10 years and we do not understand everything about the condition. Most importantly it is not clear what the best

treatment for hip impingement is. There are currently two treatment options available as standard care, physiotherapy and hip arthroscopy (explained below) and good results have been shown for both treatments, but we do not yet know if one is better than the other. There is thought to be a long-term risk of osteoarthritis in patients with hip impingement. It is not known if either of these two treatments (physiotherapy or hip arthroscopy) has any effect on this risk. In order to decide which treatment is better for patients like you in the future we need a study to compare these two treatments.

What is the purpose of this study?

This study aims to compare two different treatments for your condition - hip impingement:

- ***Personalised Hip Therapy*** – this is a new individualised and structured programme of exercise therapy designed for you by a physiotherapist. A more detailed description is provided later.
- ***Hip Arthroscopy*** – this is keyhole surgery and is designed to reshape the bone around your hip joint. A more detailed description is provided later

Why have I been invited to take part in the study?

We have invited 344 patients like you with hip impingement to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do take part you can withdraw at any time and this will not affect the care you receive.

What will happen to me if I take part?

If you decide to take part you will be asked to sign a consent form. You will then be allocated to one of the two treatments. In order to make our study work it is crucial that we have equal numbers of volunteers in each treatment group and that the one you (are invited to) join is determined by a sophisticated machine designed for this purpose, and not influenced by us. More information about the two possible treatments is given below. Whichever treatment you have, please be assured that your care will be based on meeting your individual needs, and you will continue with the same team of physiotherapists and surgeons throughout. Both these teams work closely together and they will be able to monitor your progress and share information with one another about your individual case continually. During the study we will ask you to complete 3 short questionnaires by post. You will do one questionnaire before you begin treatment and then one at 6 and 12 months after your study entry. If you need help completing a questionnaire, a researcher can contact you by phone soon after you receive it to help you complete it. We will continue to monitor your progress after 12 months via two short questionnaires at 2 and 3 years. In addition, if you have hip arthroscopy as part of the study, we will arrange for you to have a further MRI scan of your hip after the surgery. The scan will happen at least 6 weeks after your surgery and will help us to analyse the surgery that has been undertaken

Which treatments are you comparing?

The two treatments that are being compared are:

- ***Personalised Hip Therapy***-This is a personalised programme of hip therapy that is supervised by a senior physiotherapist and designed to meet your individual needs. You may already have had a course of physiotherapy for your hip, however this programme of care is different and has been designed specifically to relieve pain in your hip and improve how it works. You will meet a senior physiotherapist with a specialist interest in hip impingement who will undertake a thorough assessment of your condition including the effect it has on your life. They will then customise a specific programme of hip exercises designed to help your hip. They will teach you these exercises in clinic and you will then be able to practise these exercises at home. This programme of exercises will gradually increase in intensity and difficulty so that by the end of the programme (12 weeks) we hope you will have developed improved control and strength around your hip with less pain. In addition to the hip exercise programme, a range of additional treatments will be offered to you. These include:

    - Techniques to improve the control and strength of your posture and walking
    - Personalised advice on techniques to modify the way you undertake daily activities
    - Specific advice about pain medications to help control your pain in the initial stages of the therapy, including the possibility of a steroid injection into the hip joint if required.

  The programme lasts 12 weeks and you will need to be able to attend the physiotherapy clinic at least 3 times to be assessed, and to have your treatment progressed by your physiotherapist. In addition to this, your physiotherapist will keep a close eye on your progress over the telephone and will contact you at least 3 times in order to ensure you progress well with the programme. The exercises you will be taught will focus on muscle control and balance in the first few weeks. You will then progress to resistance and stretching exercises and activity/sport-specific exercises in later stages of the programme. You and your physiotherapist will be able to arrange an additional 2 “booster” sessions of assessment / treatment if either of you feel that more time is required to undergo the therapy after the 12 week plan is over. Your physiotherapist may feel it necessary that you have an injection of local anaesthetic and steroid into the hip joint to provide additional pain relief to allow you to complete your treatment of personalised hip therapy. This would be conducted under either local anaesthetic in the skin or sedation provided by an anaesthetist.

Hip arthroscopy The procedure is done under a general anaesthetic (you will be put to sleep). The surgeon opens up a small passage through to your hip joint using special instruments introduced through incisions on the surface of your skin. A telescope is passed through these small passages, to look inside the hip, and further instruments are inserted that allow the surgeon to reshape the hip joint and repair locally damaged tissues, such as the labrum. You will normally need to stay in hospital for between 1-3 days after the procedure. Depending on the extent of surgery, some patients have to use crutches to walk for between 6-8 weeks after the procedure. There is a period

of rehabilitation after the procedure, which will be supervised by a physiotherapist in clinic, and practised at home. It will take between 2-3 months to complete the rehabilitation programme. In addition, we will arrange for you to have a further MRI scan of your hip after the surgery. The scan will happen at least 6 weeks after your operation and will help us to analyse the surgery that has been undertaken.

What are the possible risks of taking part?

The treatments are designed to help you, however, this cannot be guaranteed. The individual risks of each treatment are outlined below:

- **Personalised Hip Therapy -** There are some small risks with pain medications and joint injections. A hip joint injection carries a very small risk of infection and bruising. However, the main risk is muscle soreness and short-term increases in pain from the exercises that you will undertake. Generally the risks of this treatment are much lower than hip arthroscopy (surgery)

- **Hip Arthroscopy –** about 1 in 50 people have specific complications from hip arthroscopy. One very rare but serious risk is a break (fracture) of the hip during the surgery. If this happened you would need an additional operation to fix the break. Other risks of hip arthroscopy include:

  - Infection within the joint or around the wounds. This can sometimes be treated with antibiotics alone. In more serious cases it requires a further procedure to washout the hip.
  - Bleeding from the wounds, but this is usually a very small amount and quickly settles.
  - Numbness in groin, leg or foot. To undertake hip arthroscopy we need to apply a pulling force on your leg in order to access the hip joint. This can cause some numbness in your groin, leg or foot as a result. This usually resolves within a few hours or days after the procedure.

For this study, both treatment options may include the use of ionising radiation, but they are not in addition to what would normally be received if they were occurring outside of this study. Although all radiation you receive builds up over your lifetime, the small doses received from either of these treatments should not create a significant risk to your health. The maximum amount of radiation from either treatment is comparable to 40 normal chest X-Ray and equivalent to 3.5 months of exposure to natural background radiation.

How do these treatments work?

Personalised Hip Therapy – this therapy works by allowing soft tissues which are damaged and painful as a result of hip impingement, such as the labrum, a period of relative rest, so that they can heal naturally. This can take up to several weeks or months. During this period you will have learnt and practised many exercises that improve the movement and control of the hip and local joints (such as your lower back and pelvis), which should ensure that your hip impingement can no longer

occur, and that damaged soft tissues, such as the labrum, can continue to heal.Hip Arthroscopy – this procedure relies on surgically removing bits of bone from around the hip so that they no longer rub together and damage the soft tissues such as the labrum. Once the bits of bone have been removed, a period of rehabilitation is required so that the soft tissues can continue to heal.

One of the long-term concerns with hip impingement is that you have an increased risk of developing arthritis of the hip. It is really important that you know that at the moment we have no evidence that any treatment (including personalised hip therapy or hip arthroscopy) will have any effect on whether you subsequently develop arthritis of your hip. However by taking part in this study it will help us in the long term to determine if either of these two treatments can help prevent arthritis.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone from our research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor. If you decide to continue in the study you might be asked to sign an updated consent form. Also, on receiving new information, we might consider it to be in your best interests to withdraw you from the study. If this happens we will explain the reasons to you and arrange for your care to continue.

What happens when the research study stops?

You will be in the study for one year. If you are still having problems after this time, we will arrange for you to see your hip specialist to continue your care.

What if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick (contact Miss Nicola Owen, Deputy Registrar, 02476 522713) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. For independent advice contact the PALS service (Patient Advice Liaison Service) at Freephone 0800 0284203.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and will not be shared with anyone outside of your direct care team. Research data including your name and address will be sent to the University of Warwick so that research staff can stay in touch with you over the course of the year, and send you follow-up questionnaires at 6 and 12 months by post. These details will be sent from the hospital by secure means, and kept in locked filing cabinets or in password-protected computer databases accessible only to essential research

personnel at the University of Warwick. All other information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. If you have hip arthroscopy an anonymised copy of your MRI will be sent electronically via a secure system to Clinical Graphics B.V. based in the Netherlands. If you agree, your GP and other doctors who may treat you, but are not part of this study, will be notified that you are taking part in this study.

What will happen to the results of the research study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please contact the study coordinator Rachel Hobson on 02476-968629 or email: ukfashion@warwick.ac.uk

Who has reviewed this project?

This study has been reviewed and approved by NRES Committee West Midlands - Edgbaston. Approval was granted on 1st May, 2014.

Contacts for further information

If at any time, you would like further information about the study, you may contact the study coordinator, Rachel Hobson, by either telephoning 02476 968629 or emailing ukfashion@warwick.ac.uk

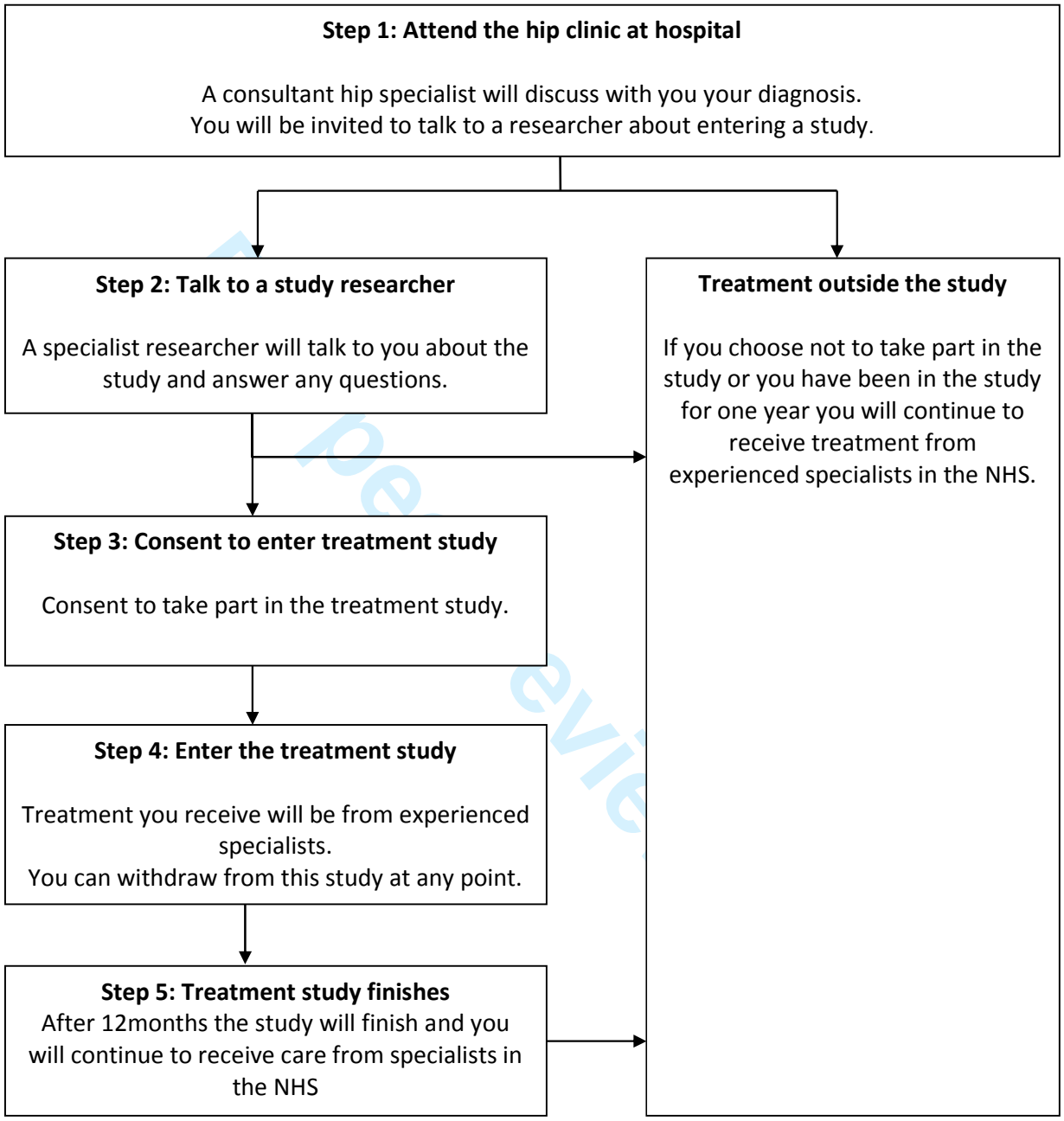
Or you can contact your local research lead, Mr Malviya Telephone 01670 529781 or Christine Dobb 0344 811 8111 extension 4561 or Professor Damian Griffin, who is the overall lead for this study on 02476 968618.

Where can I get additional information?

As well as the researcher and your surgeon who can provide advice and guidance, we have developed a website http://www2.warwick.ac.uk/fac/med/research/csri/orthopaedics/research/fulllist/fashion/

This website provides additional useful information about hip impingement and its treatments, including a series of answers to frequently asked questions. In addition, it provides internet links to other trusted sources of information.

STEP by STEP guide to the study



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UK FASHIoN

Chief Investigator: Professor Damian Griffin

CONSENT FORM – UK FASHIoN Study

Site ID | | | Participant ID: | | | |

Please **Initial** Box

1. I confirm that I have read and understand the information sheet dated 20th June, 2014– version 3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Warwick, from regulatory authorities, or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that appropriate personal identifying information will be collected, stored and used by the study office to enable follow-up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality. ☐

5. I understand that information held and managed by The Health and Social Care Information Centre and other central UK NHS bodies may be used in order to help contact me or provide information about my health status. ☐

6. I agree that encrypted anonymised copies of post-operative scans can be sent via electronic transfer to Clinical Graphics B.V. based in the Netherlands. ☐

7. I agree to my GP being informed of my participation. ☐

8. I agree to take part in the above study ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Please ensure the following: -
Original consent form retained in the site file**, 1 copy** for Patient, **1 copy** for Hospital Notes

UK FASHIoN

Recording your Consultations

Chief Investigator Professor Damian Griffin

Patient Information Sheet

You are invited to take part in a research study. Your participation in the research is completely voluntary, but your involvement would help us to care for patients like you in the future. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve – this is explained below.

What is the purpose of the research study?

The aim of this research study is to find out what information is explained to you by specialists in hip problems. The information we obtain, will help us plan future research studies looking at hip problems.

What will happen if I take part?

If you agree to take part, you will be asked to sign a consent form. During your consultations, your conversations will be recorded on a tape recorder. The recorded discussions will be written out and analysed by researchers at the University of Warwick. At any stage during the consultations, you may ask for the recording to be stopped without giving a reason.

What are the possible benefits to you of taking part?

There are no specific benefits for you in taking part. The information we get from this study will help us to plan future research studies in patients with hip problems.

Will my taking part remain confidential?

All information which is collected will be kept strictly confidential, it will not be shared with anyone outside of your direct care team. Copies of the anonymised interviews will be kept in a secure place, for 5 years, and then destroyed.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the standard of care you receive.

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you may contact Mrs Nicola Owen, deputy registrar at the University of Warwick on 02476 522785.

Who has reviewed this survey?

This study has been reviewed and approved by NRES Committee West Midlands -Edgbaston. Approval for this study was gained on 1st May, 2014.

Contacts for further information;

If you have any questions, please do not hesitate to ask your consultant at the start of your consultations. Or, for further information about this research project you may contact the study coordinator, Mrs Rachel Hobson by either telephoning 02476 968629 or emailing fashion@warwick.ac.uk, or Professor Damian Griffin, who is the overall lead of this study on 0247 6869618.

For independent advice contact the PALS service (Patient Advice Liaison Service) at freephone 0800 0284203.

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UK FASHIoN

Chief Investigator: Professor Damian Griffin

CONSENT FORM – Recording Your Consultation

Site ID ☐☐ Screening No.: ☐☐☐☐

	Please **Initial** Box
1. I confirm that I have read and understand the information sheet dated 20th June, 2014 – version 3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I give permission that anonymous quotes from my interview may be used in the reporting of this study.	☐
4. I give permission for the interview to be digitally-recorded.	☐
5. I agree to take part in the above study.	☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

Please ensure the following:
Original consent form retained in the site file, 1 copy for Patient, 1 copy for Hospital Notes.

FASHIoN Study Group

Surgeons:

E Bache (The Royal Orthopaedic Hospital NHS Foundation Trust),

M Bankes (Guys and St Thomas Hospital NHS Foundation Trust)

G Bartlett (Royal Cornwall Hospitals NHS Trust)

T Board (Wrightington, Wigan and Leigh NHS Foundation Trust)

M Cronin; (University Hospitals Coventry and Warwickshire NHS Trust),

W Dandacholi (University College London Hospitals)

S Eastaugh-Waring (North Bristol NHS Trust)

M Fehily (Spire Manchester Hospital)

E Fern (Ramsay Duchy Hospital)

R Field; (Southwest London Elective Orthopaedic Centre)

M George (Guys and St Thomas Hospital NHS Foundation Trust)

A Hashimi-Nejad (Royal National Orthopaedic Hospital NHS Trust)

V Kavathapu (King's College Hospital NHS Foundation Trust)

T Khan (Royal National Orthopaedic Hospital NHS Trist),

N Kiely; (Robert Jones and Agnes Hunt Orthopaedic and District Hospital)

P Latimer (Yeovil District Hospital NHS Trust)

S Madan (Doncaster and Bassetlaw Hospitals NHS Foundation Trust)

A Malviya (Northumbria NHS Trust)

C Mcbryde (The Royal Orthopaedic Hospital NHS Foundation Trust),

A Mohammed (Wrightington, Wigan and Leigh NHS Foundation Trust)

M Norton (Royal Cornwall Hospitals NHS Trust)

S Patil, (NHS Greater Glasgow and Clyde)

A Politis (The Royal Orthopaedic Hospital NHS Foundation Trust)

A Rajpura (Wrightington, Wigan and Leigh NHS Foundation Trust)

M Ramachandran (Bart's Health NHS Trust)

G Stafford (Southwest London Elective Orthopaedic Centre)

S Sturridge (Frimley Health NHS Foundation Trust)

P Thomas (Cardiff and the Vale University Health Board)

C White (South Tees Hospitals NHS Foundation Trust)

M Wilson (Royal Devon and Exeter NHS Trust)

JP Whitaker (Robert Jones and Agnes Hunt Orthopaedic and District Hospital and Wrexham Maelor Hosital)

M Williams (Plymouth Hospitals NHS Trust)

J Witt (University College London Hospitals)

Physiotherapists:

E Jones Yeovil District Hospital

S Baker Yeovil District Hospital

J Stanton Yeovil District Hospital

C Nicholls Yeovil District Hospital

A Smeatham Royal Devon & Exeter NHS Foundation Trust

L Gosling The Royal Orthopaedic Hospital NHS Foundation Trust

G Dickinson Frimley Park Hospital
K Boulton Frimley Health NHS Trust
J Goss Epsom and St Hellier NHS Trust
R Venter Guys and St Thomas Hospital NHS Foundation Trust
A Bennett Bart's Health NHS Trust
R Simmons University College London Hospitals NHS Trust
K Poll University College London Hospitals NHS Trust
T Bergmann University College London Hospitals NHS Trust
M Pilkington Wrightington, Wigan and Leigh NHS Foundation Trust
J Armstrong Wrightington, Wigan and Leigh NHS Foundation Trust
D Wright Wrightington, Wigan and Leigh NHS Foundation Trust
P Dolphin James Cook University Hospital
K Bainbridge James Cook University Hospital
M Callum Wansbeck General Hospital
S Lewis Wansbeck General Hospital
E Smith Wansbeck General Hospital
V Cornes University Hospitals Coventry and Warwickshire
I Hughes University Hospitals Coventry and Warwickshire
J Benfield Royal National Orthopaedic Hospital
K Monnington Royal National Orthopaedic Hospital
E Stewart Royal National Orthopaedic Hospital
S Borrill Doncaster Royal Infirmary
M Hyne, Robert Jones and Agnes Hunt Orthopaedic Hospital
N Harding Robert Jones and Agnes Hunt Orthopaedic Hospital
S Dawson Wrexham Maelor Hospital
M Willis Wrexham Maelor Hospital
D Moore Kings College Hospital
F Pressdee The Royal Orthopaedic Hospital NHS Trust
K MacFarlane The Royal Orthopaedic Hospital NHS Trust
A MacCauley St Austell Community Hospital
D Cooke Royal Cornwall Hospitals NHS Trust
B Fleck University Hospitals Cardiff
P Dowrick Derriford Hospital
J Ball North Britsol NHS Trust
P Morrison NHS Greater Glasgow and Clyde
C O'Donnell NHS Greater Glasgow and Clyde
M Kennedy Spire Manchester Hospital

Recruiters:
S Turner University Hospitals Coventry and Warwickshire
C Bryant University Hospitals Coventry and Warwickshire
K Baddick University Hospitals Coventry and Warwickshire
R McKeown University Hospitals Coventry and Warwickshire
L Clarkson University Hospitals Coventry and Warwickshire
A Lewis Yeovil District Hospital

R Rowland-Axe Yeovil District Hospital
A Grice Royal Devon and Exeter NHS Trust
G Githens-Mazer Royal Devon and Exeter NHS Trust
H Aughwan The Royal Orthopaedic Hosptial NHS Trust
F Moore The Royal Orthopaedic Hosptial NHS Trust
E Keeling The Royal Orthopaedic Hosptial NHS Trust
J Amero Frimey Park NHS Foundation Trust
S Atkinson Frimey Park NHS Foundation Trust
L Graves Royal Cornwall Hospitals NHS Trust
E Fouracres Royal Cornwall Hospitals NHS Trust
J Curtis South West London Elective Orthopaedic Centre
T Kadiyirire Guys and St Thomas Hospital NHS Foundation Trust
L Brackenridge University College London Hosptial
T Taylor Wrightington, Wigan and Leigh NHS Foundation Trust
C Dobb Northumbria NHS Trust
J Hinchliffe Doncaster and Bassetlaw Hospitals NHS Foundation Trust
V Limbani Royal National Orthopaedic Hospital NHS Trist)
A Milne South Tees Hospitals NHS Foundation Trust
H Maclintock Wrexham Maelor Hospital
C Cleary Cardiff and the Vale University Health Board
H Murray NHS Greater Glasgow and Clyde
M Dubia King's College Hospital NHS Foundation Trust
R Bray North Bristol NHS Trust
R Squire Plymouth Hospitals NHS Trust
F Hammonds Royal Cornwall Hospitals NHS Trust

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	4
Protocol version	3	Date and version identifier	6
Funding	4	Sources and types of financial, material, and other support	20-21
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	21
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11-12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15 (+ figure1)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8, 13-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11-12

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8-9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19-20
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	See full trial protocol.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
	31b	Authorship eligibility guidelines and any intended use of professional writers	1
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Protocol for a multi-centre, parallel-arm, 12-month, randomised controlled trial of arthroscopic surgery versus conservative care for femoroacetabular impingement syndrome (FASHIoN).

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Protocol for a multi-centre, parallel-arm, 12-month, randomised controlled trial of arthroscopic surgery versus conservative care for femoroacetabular impingement syndrome (FASHIoN).

Authors and affiliations:

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Contributorship Statement

DG is the Chief Investigator of the FASHIoN Trial. DG led the conception, design, acquisition, analysis and interpretation of data. DG contributed to drafting and approved the final submitted version of this manuscript.

ED contributed to the design, acquisition, analysis and interpretation of the data. ED contributed to the drafting and approved the manuscript.

PW contributed to the conception, design and acquisition of the trial data. PW contributed to drafting the manuscript and approved the final version

JLD contributed to the conception, design and analysis of trial date. JLD contributed to the drafting and approved the manuscript.

NEF contributed to the conception, design, analysis and interpretation of the trial data. NEF contributed to the drafting and approved the manuscript.

CEH contributed to the design and analysis of the trial data. CH contributed to the drafting and approved the manuscript.

NP contributed to the conception, design, analysis and interpretation of the data. NP contributed to the drafting and approved the manuscript.

SP contributed to the conception, design and interpretation of the data for the trial. SP contributed to the drafting and approved the manuscript.

AR contributed to the acquisition, analysis and interpretation of the trial data. AR contributed to the drafting and approved the manuscript.

JA contributed to the conception, design and analysis of the trial data. JA contributed to the drafting and approved the manuscript.

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AA contributed to the conception and design of the trial. AA contributed to the drafting and approved the manuscript.

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Abstract

Introduction

Femoroacetabular impingement (FAI) syndrome is a recognised cause of young adult hip pain. There has been a large increase in the number of patients undergoing arthroscopic surgery for FAI, however a recent Cochrane review highlighted that there are no randomised controlled trials evaluating treatment effectiveness.

We aim to compare the clinical and cost effectiveness of arthroscopic surgery versus best conservative care for patients with symptoms of FAI syndrome.

Methods,

We will conduct a multi-centre, pragmatic, assessor blinded, two parallel arm, randomised controlled trial comparing arthroscopic surgery to physiotherapy led best conservative care. Twenty-four hospitals treating NHS patients will recruit 344 patients over a 26-month recruitment period. Symptomatic adults with radiographic signs of FAI morphology who are considered suitable for arthroscopic surgery by their surgeon will be eligible. Patients will be excluded if they have radiographic evidence of osteoarthritis, previous significant hip pathology or previous shape changing surgery. Participants will be allocated in a ratio of 1:1 to receive arthroscopic surgery or conservative care. Recruitment will be monitored and supported by qualitative intervention to optimise informed consent and recruitment.

The primary outcome will be pain and function assessed by the international hip outcome tool 33 (iHOT-33) measured 1 year following randomisation. Secondary outcomes include general health (short form 12), quality of life (EQ5D-5L) and patient satisfaction. The primary analysis will compare change in pain and function (iHOT-33) at 12 months between the treatment groups, on an intention-to-treat basis, presented as the mean difference between the trial groups with 95% confidence intervals.

The study is funded by the Health Technology Assessment Programme (13/103/02).

Ethics and Dissemination:

Ethical approval is granted by the Edgbaston Research Ethics committee (14/WM/0124). The results will be disseminated through open access peer-reviewed publications, including *Health Technology Assessment*, and presented at relevant conferences.

Word count: 295

Trial Registration:

ISRCTN64081839

Strengths and Limitations

- This trial is multi-centre, pragmatic and randomised making results generalisable across the NHS.
- Further strengths include a large sample size and the robust procedures to assess treatment fidelity.

Background

Until recently, there was little understanding of the causes of hip pain in young adults. Since first described in 2003 there has been increasing recognition of the syndrome of femoroacetabular impingement (FAI), which seems to account for a proportion of the previously undiagnosed cases of hip pain in young adults.[1 2] Subtle deformities of hip shape combine to cause premature contact between the femoral neck and the acetabular rim which may result in hip pain.[1 3] These shape abnormalities typically divide into three categories:[3 4]

- Cam-type, in which the femoral head is oval rather than round, or there is bony prominence on the femoral neck;
- Pincer-type, in which the rim of the acetabulum is excessively prominent, in one or more areas of its circumference;
- Mixed-type hip impingement, a combination of cam and pincer types.

Surgery can be performed to reshape the bony contour of the proximal femur and/or acetabular rim in order to prevent impingement. Surgery for FAI has evolved more quickly than our understanding of the epidemiology or natural history of the condition,[5 6] and is becoming an established treatment for FAI.[7] The risks of complications from open surgery are greater than those for arthroscopic surgery and current evidence suggests that the outcomes of arthroscopic treatment for the symptoms of FAI are comparable to open surgery.[8] [9] Consequently, hip arthroscopy for FAI is a rapidly growing new cost pressure for health providers.[10] However a recently published Cochrane review highlighted the absence of randomised controlled trials comparing FAI surgery with conservative care such as physiotherapist-led exercise.[11] Physiotherapy has also been shown to be beneficial in patients with FAI syndrome.[12] [13] During a successful feasibility study (HTA 10/41/02) a programme of physiotherapist-led conservative care was developed called personalised hip therapy (PHT).[14]

Aims of Trial

We aim to compare the clinical and cost effectiveness of arthroscopic surgery versus physiotherapist-led conservative care (PHT) in patients with symptoms of FAI syndrome.

Methods/ Design

This trial will be conducted in accordance with the Medical Research Council's Good Clinical Practice principles and guidelines, the Declaration of Helsinki, Warwick Clinical Trials Unit (WCTU) standard operating procedures (SOPs), relevant UK legislation and the trial protocol. Ethical approval was granted on 1/5/2014 (14/WM/0124), by the Edgbaston Research Ethics committee (current approved protocol version 3.1 20/01/2016). The trial will be reported in line with the CONSORT statement. This full trial follows a successful feasibility and pilot trial (HTA10/41/02).[14]

Trial Design and Setting

This is a protocol for the **f**ull UK randomised controlled trial of **a**rthroscopic **s**urgery for **h**ip **i**mpingement versus best c**on**servative care (**FASHIoN**). We will conduct a multi-centre, pragmatic, assessor blinded, parallel arm, 12-months, 1:1 randomised controlled trial of hip arthroscopy versus conservative care for FAI assessing patient pain, function, general health, quality of life, satisfaction and cost effectiveness. There is an integrated qualitative recruitment intervention (QRI) that includes interviews with recruiters and patients, and observations of recruitment appointments to ensure patients have the opportunity to fully consider participation in the trial.[15]

We hypothesise that arthroscopic surgery is superior to conservative care at 12 months for self reported hip pain and function for patients with FAI syndrome.

The trial will be conducted on consenting patients treated in the NHS. Hospitals participating in FASHIoN will have an organised hip arthroscopy service treating at least 20 patients with arthroscopic surgery for FAI per year.

Target Population

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

Inclusion criteria

- Age ≥16 (no upper age limit);
- Symptoms of hip pain - patients may also have symptoms of clicking, catching or giving way;
- Radiographic evidence of pincer- and/or cam-type FAI morphology on plain radiographs and cross-sectional imaging, defined as:
    - Cam morphology - an alpha angle >55º [16]
    - Pincer morphology - a lateral centre edge angle of >40º or a crossover sign on the anteroposterior radiograph of the pelvis [17]
- The treating surgeon believes the patient would benefit from arthroscopic FAI surgery;
- The patient is able to give written informed consent and to participate fully in the interventions and follow-up procedures.

Exclusion criteria

- Evidence of pre-existing osteoarthritis, defined as Tonnis grade >1, [18] or more than 2mm loss of superior joint space width on anterio-posterior pelvic radiograph;[19]
- Previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis, or avascular necrosis;
- Previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture;
- Previous shape changing surgery (open or arthroscopic) in the hip being considered for treatment.

198

199 **Participant identification, invitation, recruitment and baseline data**
200 **collection**

201 Patients who complain of hip pain, who do not already have a diagnosis of hip
202 osteoarthritis, will be identified as potential participants by screening referral
203 letters to collaborating surgeons. Research nurses/associates will keep accurate
204 screening logs to identify if these potential participants meet the eligibility criteria.
205 Once diagnosed with FAI by the surgeon, and deemed eligible for the trial, the
206 patient will be given a trial information sheet (see supplementary files 1 and 2)
207 and referred to a trained recruiter for a trial information consultation. During this
208 consultation patients can discuss the trial, participation will be offered, and
209 informed consent obtained (see supplementary files 3 and 4). It will be explained
210 that participation is voluntary and patients can withdraw at any time. Once
211 consent is obtained, and prior to treatment allocation, baseline patient reported
212 outcomes will be collected (see outcome measures below).
213
214 In order to optimise recruitment and informed consent trained qualitative
215 researchers will observe recordings of the surgeons' and research
216 associate/nurses' trial information consultations (see supplementary files 2 and
217 4), to identify communication patterns that facilitate or hinder patient
218 recruitment.[15] See Figure 1 – Flow Diagram. In-depth interview with the
219 recruiters will be undertaken to identify clear obstacles and hidden challenges to
220 recruitment, including the influence of patient preferences and equipoise.[20]
221 Research teams will be interviewed to identify clinician equipoise, patient
222 pathway from eligibility to consent, and staff training needs at each participating
223 site.[15] Findings will be fed back to the CI and trial management group (TMG)
224 so that practice can be reviewed and any necessary changes (including
225 additional training) implemented. The number of eligible patients, the
226 percentages of these that are approached and consented to be randomised will
227 be monitored at each site.

This research will be linked, through Donovan, to the Quintet programme of research within the MRC ConDuCT-II (Bristol) Trial Methodology Hub.

<insert figure 1 "Figure 1 Participant Flow Diagram">

Randomisation

Participants will be randomised, in a 1:1 ratio, to arthroscopic surgery or PHT using a computer generated sequence. Allocation will be made by the research nurse/associate via a centralised telephone randomisation service provided remotely by WCTU. Allocation concealment will be ensured, as the randomisation programme will not release the randomisation code until the patient has been recruited into the trial. In order to improve baseline balance between intervention group samples, a minimisation (adaptive stratified sampling) algorithm will be implemented using study site and impingement type (cam, pincer or mixed) factors. Research nurses/ associates who recruit participants will ensure they are referred for the allocated intervention. Patients and clinicians cannot be blind to treatment allocation. However outcome assessors will be blind to the treatment delivered.

Interventions

The two interventions will commence as soon as possible after randomisation. We will record dates of randomisation and the start of allocated treatment. As this is a pragmatic trial subjects were not prohibited from undergoing any additional/ concomitant care.

Arthroscopic Surgery

Arthroscopic surgery will be completed by a Consultant Surgeon delivering hip arthroscopy as part of their routine practice. Arthroscopic hip surgery will be performed under general anaesthesia according to the surgeon's usual practice. Shape abnormalities and consequent labral and cartilage pathology will be

treated. Bony resection at the acetabular rim and at the head-neck junction will be assessed by intraoperative image intensifier radiographs and/or satisfactory impingement free range of movement of the hip. Patients will be allowed home when they can walk safely with crutches (usually within 24 hours). On discharge patients will be referred for a course of rehabilitation as per usual care for that surgeon. We will not specify a protocol for this post-operative physiotherapy, but will record the surgeons' routine post op care and any case-by-case changes to this. Care will be taken to ensure that physiotherapists delivering post-operative care to FASHIoN trial participants are different from those trained and providing PHT in order to avoid contamination between groups. Patients will also have a post-operative MRI after 6 weeks.

In order to ensure the fidelity of the surgery and to identify participants for a secondary analysis, a panel of international experts will review operation notes, intra operative images and post-operative MRI scans to assess whether adequate surgery was undertaken. This panel includes: Mark Philippon (USA), Martin Beck (Switzerland), John O'Donnell (Australia) and Professor Charles Hutchinson (UK).

Personalised Hip Therapy (PHT)

PHT is a package of physiotherapist-led best conservative care for FAI. It was developed during the feasibility study and 'road-tested' during the pilot trial (HTA 10/41/02).[14] The care being offered represents a consensus of what physiotherapists, physicians and surgeons regard as 'best conservative care' for FAI. PHT will be delivered by a senior physiotherapist at each site, who will be trained at a FASHIoN PHT workshop, and supported in PHT delivery by a physiotherapy research facilitator.

PHT consists of four key components:

1) An assessment of pain, function and range of hip motion,
2) Patient education and advice

3) Help with pain relief (which may include up to one radiographic guided intra-articular steroid injection where pain prevents performance of the exercise programme)
4) An exercise programme that has the key features of individualisation, progression and supervision.

The intervention is delivered over a minimum of 6 patient contacts (at least 3 of which must be face-to-face treatment contacts, others can be by telephone and email) over a period of 6 months. In situations where the patient needs additional review, support or guidance, further sessions with the physiotherapist are permitted upto a maximum of 10 contacts. Evidence of exercise individualisation, supervision and progression will be sought from individual participant physiotherapy case report forms (CRFs). Accuracy of CRFs will be audited against the physiotherapist's treatment notes.

The PHT CRFs will be assessed for intervention fidelity to identify participants for a secondary analysis by the panel that developed the protocol for PHT including: Professor Nadine Foster (Senior Academic Research Physiotherapist), Ivor Hughes and David Robinson (UK; Extended Scope Musculoskeletal Physiotherapists) and Peter Wall (Academic Orthopaedic Surgeon).

Cross-over of participants between interventions can be problematic in trials of this nature. In order to minimise this care will be taken prior to enrollment in the trial to ensure potential participants:

- Are willing to receive either intervention.
- Understand both treatments are thought to provide benefit
- Are willing to remain with their allocation for 12 months.
- Understand that both interventions may take 6 months to improve symptoms.[12 19]

In instances where patients are not satisfied with how their treatment is progressing prior to reaching the primary outcome they will be able to have a further consultation with their treating surgeon where they would be treated in

their best interests.

Risks and benefits

Both interventions are thought to provide benefit in patients with FAI. The short-term risks of this study relate to the two interventions. These risks are described below and inform the expected serious adverse events (SAEs):

Hip arthroscopy requires a general anaesthetic. The risk of complications from hip arthroscopy is about 1-2%[45]. These include:

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

PHT

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

Outcome Measures

Baseline data will be collected from participants once consent is obtained and prior to randomisation. Follow up questionnaires will be administered centrally by a data clerk via post. If participants fail to respond they will be contacted via

telephone, email or via their next of kin where necessary. Table 1 lists the data collected and at which follow up time points.

Primary Outcome

The primary outcome measure is hip pain, function and hip related quality of life using the **International Hip Outcome Tool-33** (iHOT-33) at 12 months following randomisation. iHOT-33 is a validated hip specific patient-reported outcome tool which measures health-related quality of life in young, active patients with hip disorders[21]. It consists of the following domains: symptoms and functional limitations, sports and recreational activities, job related concerns and social, emotional and lifestyle concerns.

We chose it following our feasibility and pilot study as:

- It is more sensitive to change than other hip outcome tools,[21]
- It does not show evidence of floor or ceiling effects in patients undergoing hip arthroscopy,[21]
- Patients were involved extensively in item generation; so we can be confident that it measures what is most important to patients,[21]
- There is an independently determined minimally clinically important difference (MCID),[21]
- It is used as the principal outcome measure for the UK Non-Arthritic Hip Registry; mandated for arthroscopic FAI surgery by the National Institute of Health and Clinical Excellence (NICE).[10]

Secondary Outcome Measures

Health related quality of life: **EQ-5D 5L**. This is a validated measure of health-related quality of life, consisting of a five dimension health status classification system and a separate visual analogue scale. EQ-5D is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status.[22] Responses will be converted into health utility scores using established algorithms.[23]

General health: **Short Form-12 Health Survey V2**. This is a validated and widely-used health-related quality of life measure particularly including hip conditions and treatments.[24] SF-12 is able to produce the physical and mental component scales originally developed from the SF- 36 with considerable accuracy but with far less respondent burden.[25] Responses will be converted into health utility scores using established algorithms.[26]

Patient satisfaction using questions that our team (Foster) has used in previous trials with musculoskeletal pain patients,[27] we will measure two distinct dimensions of satisfaction in all participants during follow-up: '*Overall, how satisfied are you with the treatment you received?'* and *'Overall*, *how satisfied are you with the results of your treatment?'* Responses are on a 5-point Likert scale. These questions are in line with previous studies of patient satisfaction which show that the majority of patients express overall satisfaction with the care they received, but fewer express overall satisfaction with the clinical outcomes resulting from their care.

Qualitative assessment of outcome; we will conduct in-depth interviews one-to-one with a purposively selected sample of 25-30 participants in each of the trial groups, including older and younger, male and female, more and less active, and more and less satisfied participants recruited at different trial sites. The qualitative interviews will supplement the quantitative outcomes. Interviews will explore experiences of the trial processes, the treatments, and the consequences of treatment to participants' lives, health and wellbeing.

Adverse Events We will record number and type of adverse events (AEs) up to 12 months. Any AEs will be reported on the appropriate CRF and returned to WCTU. Any SAEs will be faxed to WCTU, within 24hours of the local investigator becoming aware, where the Chief Investigator will determine causality and expectedness. SAEs deemed unexpected and related to the trial will be reported to the research ethics committee within 15days.

Resource utilisation Information on health care resource use will be collected by incorporating questions within the patient follow-up questionnaires. We confirmed the feasibility and acceptability of this approach in our pilot trial, and patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.[28]

Need for further procedures We will record any further treatments performed in both groups, such as hip arthroscopy, open hip preservation surgery, hip replacement, or additional "out of trial" physiotherapy. We propose to ascertain the need for further procedures by questionnaire at two and three years. We also propose a 5 and 10-year no-cost ascertainment of hip replacement by linkage to the UK National Joint Registry (NJR) and Hospital Episode Statistic (HES) databases.

Table 1 Data Collection Time points

Time point	Data collection
Baseline	Demographics, physical activity (UCLA Activity Scale),[29] iHOT-33, SF-12,EQ-5D Preoperative imaging, economics questionnaire.
Intervention	Operation notes and photographs; or PHT log. Complications records 6 weeks post start of intervention. Post-op MRI (surgery intervention only)
6 months	iHOT-33, SF-12, EQ-5D, resource utilisation, adverse events
12 months (primary outcome)	iHOT-33, SF-12, EQ-5D, patient satisfaction, resource utilisation, adverse events
2 years	Further procedures questionnaire
3 years	Further procedures questionnaire
5 & 10 years	Linkage to National Joint Registry and HES to identify need for hip replacement

Sample Size Calculation

The development work for iHOT-33 reported a mean iHOT-33 score of 66 and a standard deviation of 19.3 in a heterogeneous population with a variety of hip

pathologies. The baseline iHOT-33 data from our pilot trial (HTA grant 10/41/02) suggests the target population of patients being considered for hip arthroscopy for FAI have lower scores with less variability, with a mean of 33 and SD of 16. The MCID for iHOT-33 in this population is 6.1 points.[21]

Our sample size calculation is therefore based on a SD of 16 and a between group MCID of 6.1: a standardised effect difference between groups at 12 months of 0.38. The expected sample size for 90% power to detect an effect size of 0.38 at 12 months, at a 5% significance level, assuming an approximately normal distribution of the iHOT-33 score is 292. Allowing for 15% loss to follow-up at 12 months, we will recruit a sample of 344 participants over 26months in the UK (172 in each group).

Statistical Analysis

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

The minimisation randomisation procedure should ensure treatment group balance across recruiting sites. We have no reason to expect that clustering effects will be important for this study, but the possibility of such effects will be explored as part of the analysis.[33] We plan to account for clustering by generalising a conventional linear (fixed-effects) regression approach to a mixed-effects modelling approach; where patients are naturally grouped by recruiting sites (random-effects) and, if amenable to analysis, also by physiotherapist and surgeon. This model will formally incorporate terms that allow for possible heterogeneity in responses for patients due to the recruiting centre, in addition to the fixed effects of the treatment groups, and patient characteristics that may prove to be important moderators of treatment effect such as age, gender and FAI type. This analysis will be conducted using specialist mixed-effects modelling functions available in the software packages Stata (StataCorp. 2015. Stata

Statistical Software: Release 14. College Station, TX: StataCorp LP) and R (http://www.r-project.org/). All tests will be two-sided and considered to provide evidence for a statistically significant difference if p-values are less than 0.05 (5% significance level).

Secondary analyses will be performed using the above strategy for other approximately normally distributed outcome measures including iHOT-33 at 6 months, SF-12 (and computed sub-scales) and EQ5D. Differences in dichotomous outcome variables such as adverse events, complications related to the trial interventions and the need for further procedures will compared between groups using chi-squared tests (or Fisher's exact test) and mixed effects logistic regression analysis will be undertaken, adjusting for the stratifying variables, with differences between trial intervention groups quantified as odds ratios (and 95% confidence intervals). The temporal patterns of any adverse events will be presented graphically and if appropriate a time-to-event analysis (Kaplan-Meier survival analysis) will be used to assess the overall risk and risk within individual classes of adverse events. Ordinal scores for patient satisfaction will be compared between intervention groups using proportional odds logistic regression analysis, assuming that the estimated intervention effect between any pair of categories is equivalent.

Our inferences will be drawn from the intention to treat-analysis. We will perform two exploratory secondary analyses. One will compare patients who received surgery and those who received conservative care. A second exploratory analysis will compare patients randomised to surgery or PHT and received treatment deemed to be of a high fidelity by the respective review panels. We plan to perform a subgroup analysis by FAI type because it is possible that treatment effect is moderated by type. We anticipate that adequate steps have been taken to prevent crossovers from being a major issue for this study. Therefore we expect the main intention-to-treat analysis to provide definitive results. An independent Data Monitoring Committee (DMC) will monitor crossovers and adherence to treatment and advise on appropriate modifications to the statistical analysis plan as the full trial progresses.

The initial feasibility and pilot studies (HTA 10/41/02) were designed explicitly to assess feasibility and measure recruitment rates, and not to estimate treatment effectiveness. Data from the pilot will be pooled with data from the full trial, and analysed together.

Economic Analysis

An economic evaluation will be integrated into the trial design and will be conducted from the recommended NHS and personal social services perspective.[30] Cost-effectiveness will be calculated using both within trial and lifetime horizons. Data will be collected on the health and social service resources used in the treatment of each trial participant until 12 months.
An incremental cost-effectiveness analysis, expressed in terms of incremental cost per quality-adjusted life year gained, will be performed. Results will be presented using incremental cost-effectiveness ratios and cost-effectiveness acceptability curves generated via non-parametric bootstrapping.

Qualitative Interview Analysis

Participant interview transcripts will be analysed thematically, using methods of constant comparison derived from grounded theory.[31] Emerging themes will be explored, looking for shared or disparate views among patients about their experiences, and among clinicians about their experiences of delivering the trial interventions. Focused conversation analysis will be undertaken on sections of recruitment appointments, and compared with the six-step good recruitment model developed in the pilot study to identify aspects of RCT presentation that are unclear, disrupted or hinder recruitment.[15 20 32]

Data Management

All of the data collected in this trial will be entered into a secure trial database held at WCTU. All data collected will be anonymised after the collection of baseline demographic data, and all participants given a unique trial number.

Identifiable participant data will be held in a locked filing cabinet and coded with a trial participant number to tag identifiable data to the outcome data. The WCTU quality assurance manager will undertake audits of trial records in accordance with WCTU SOPs.

A DMC will be established comprised of members who are independent of the sponsor and who do not have competing interests. The DMC will review trial progress, interim data and safety aspects of the trial. They will also review the statistical analysis plan. Any recommendations will be fed back to the trial steering committee (TSC) by the DMC chair. Outcomes will not be analysed until all primary outcome data are collected. The trial may be stopped pre-maturely if mandated by the research ethics committee, the DMC or if funding ceases.

Discussion

This protocol paper describes the FASHIoN trial; a multicenter RCT comparing hip arthroscopy to best conservative care (PHT) in order to establish the most clinically and cost-effective treatment for patients with FAI syndrome. Further details of the trial protocol can be found on the ISRCTN registry (ISRCTN64081839). This protocol will also be used for a randomised trial in Australia (ACTRN12615001177549). The results of the trial will be disseminated at international meetings and in peer reviewed journals; to participants via post and to the public via the trial website.

The main strengths of this trial are that it is multi-center, pragmatic and randomised making results generalisable across the NHS. Further strengths include a large sample size and the robust procedures to assess treatment fidelity.

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The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing Interests:

The Chief Investigator and many of the co-investigators are Orthopaedic Surgeons who perform FAI surgery in the NHS and within private practice.

Ethics Approval: Ethical approval was granted on the 12th Febuary 2012 (11/WM0389) and on the 1st of May 2014 (14/WM/0124), by the Edgbaston Research Ethics committee.

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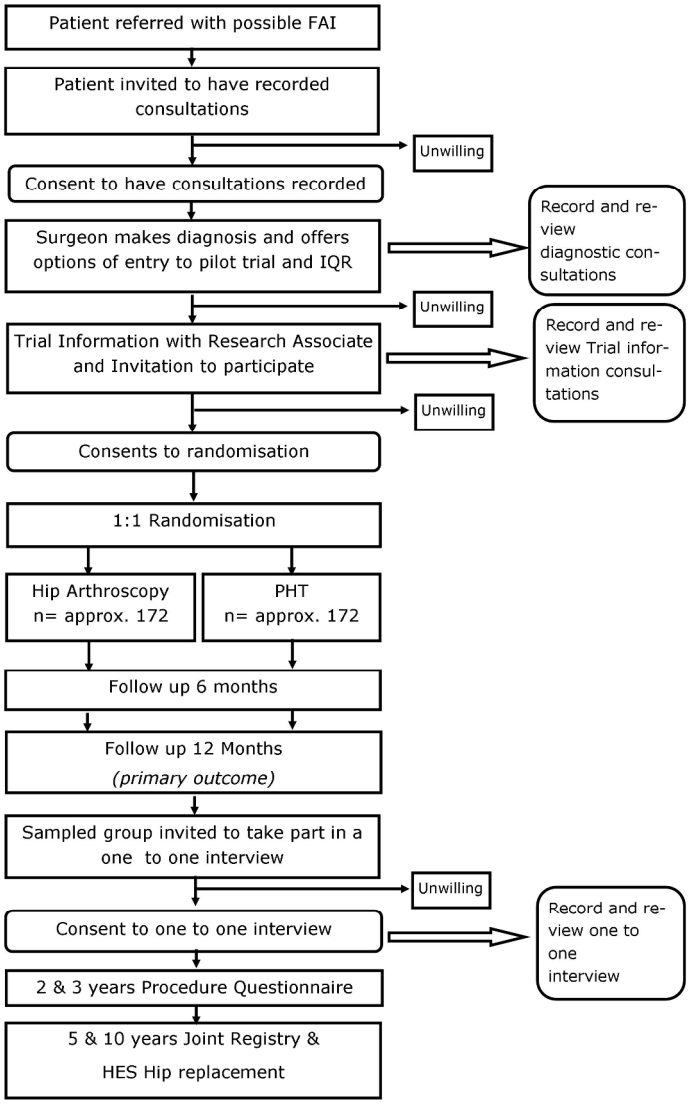


Figure 1 Flow Diagram
209x297mm (300 x 300 DPI)

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

UK FASHIoN Study

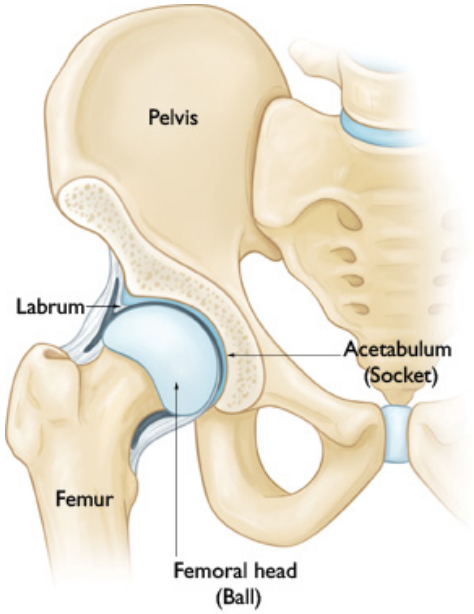
Chief Investigator: Professor Damian Griffin

Patient Information Sheet

You are invited to take part in our research study. Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. Once you have had a chance to read and absorb this information sheet a member of our team will personally go through the information with you and answer any questions you may have.

Background Information

Your hip joint has two bones that fit together like a ball in a socket, see figure 1.



- Figure 1 – Normal Hip Joint

The bones that make the ball and socket joint are not the same shape in everyone. In some people with a shape similar to yours the bones press against each other and damage the local soft tissues such as the labrum (a soft cushioning around the hip joint- see figure 1) which can cause pain.

This is called Hip Impingement and the medical term for this is femoroacetabular impingement (FAI for short). Hip impingement has only been discovered in the last 10 years and we do not understand everything about the condition. Most importantly it is not clear what the best

treatment for hip impingement is. There are currently two treatment options available as standard care, physiotherapy and hip arthroscopy (explained below) and good results have been shown for both treatments, but we do not yet know if one is better than the other. There is thought to be a long-term risk of osteoarthritis in patients with hip impingement. It is not known if either of these two treatments (physiotherapy or hip arthroscopy) has any effect on this risk. In order to decide which treatment is better for patients like you in the future we need a study to compare these two treatments.

What is the purpose of this study?

This study aims to compare two different treatments for your condition - hip impingement:

- ***Personalised Hip Therapy*** – this is a new individualised and structured programme of exercise therapy designed for you by a physiotherapist. A more detailed description is provided later.
- ***Hip Arthroscopy*** – this is keyhole surgery and is designed to reshape the bone around your hip joint. A more detailed description is provided later

Why have I been invited to take part in the study?

We have invited 344 patients like you with hip impingement to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do take part you can withdraw at any time and this will not affect the care you receive.

What will happen to me if I take part?

If you decide to take part you will be asked to sign a consent form. You will then be allocated to one of the two treatments. In order to make our study work it is crucial that we have equal numbers of volunteers in each treatment group and that the one you (are invited to) join is determined by a sophisticated machine designed for this purpose, and not influenced by us. More information about the two possible treatments is given below. Whichever treatment you have, please be assured that your care will be based on meeting your individual needs, and you will continue with the same team of physiotherapists and surgeons throughout. Both these teams work closely together and they will be able to monitor your progress and share information with one another about your individual case continually. During the study we will ask you to complete 3 short questionnaires by post. You will do one questionnaire before you begin treatment and then one at 6 and 12 months after your study entry. If you need help completing a questionnaire, a researcher can contact you by phone soon after you receive it to help you complete it. We will continue to monitor your progress after 12 months via two short questionnaires at 2 and 3 years. In addition, if you have hip arthroscopy as part of the study, we will arrange for you to have a further MRI scan of your hip after the surgery. The scan will happen at least 6 weeks after your surgery and will help us to analyse the surgery that has been undertaken

Which treatments are you comparing?

The two treatments that are being compared are:

- ***Personalised Hip Therapy***-This is a personalised programme of hip therapy that is supervised by a senior physiotherapist and designed to meet your individual needs. You may already have had a course of physiotherapy for your hip, however this programme of care is different and has been designed specifically to relieve pain in your hip and improve how it works. You will meet a senior physiotherapist with a specialist interest in hip impingement who will undertake a thorough assessment of your condition including the effect it has on your life. They will then customise a specific programme of hip exercises designed to help your hip. They will teach you these exercises in clinic and you will then be able to practise these exercises at home. This programme of exercises will gradually increase in intensity and difficulty so that by the end of the programme (12 weeks) we hope you will have developed improved control and strength around your hip with less pain. In addition to the hip exercise programme, a range of additional treatments will be offered to you. These include:

  - Techniques to improve the control and strength of your posture and walking
  - Personalised advice on techniques to modify the way you undertake daily activities
  - Specific advice about pain medications to help control your pain in the initial stages of the therapy, including the possibility of a steroid injection into the hip joint if required.

  The programme lasts 12 weeks and you will need to be able to attend the physiotherapy clinic at least 3 times to be assessed, and to have your treatment progressed by your physiotherapist. In addition to this, your physiotherapist will keep a close eye on your progress over the telephone and will contact you at least 3 times in order to ensure you progress well with the programme. The exercises you will be taught will focus on muscle control and balance in the first few weeks. You will then progress to resistance and stretching exercises and activity/sport-specific exercises in later stages of the programme. You and your physiotherapist will be able to arrange an additional 2 “booster” sessions of assessment / treatment if either of you feel that more time is required to undergo the therapy after the 12 week plan is over. Your physiotherapist may feel it necessary that you have an injection of local anaesthetic and steroid into the hip joint to provide additional pain relief to allow you to complete your treatment of personalised hip therapy. This would be conducted under either local anaesthetic in the skin or sedation provided by an anaesthetist.

Hip arthroscopy The procedure is done under a general anaesthetic (you will be put to sleep). The surgeon opens up a small passage through to your hip joint using special instruments introduced through incisions on the surface of your skin. A telescope is passed through these small passages, to look inside the hip, and further instruments are inserted that allow the surgeon to reshape the hip joint and repair locally damaged tissues, such as the labrum. You will normally need to stay in hospital for between 1-3 days after the procedure. Depending on the extent of surgery, some patients have to use crutches to walk for between 6-8 weeks after the procedure. There is a period

of rehabilitation after the procedure, which will be supervised by a physiotherapist in clinic, and practised at home. It will take between 2-3 months to complete the rehabilitation programme. In addition, we will arrange for you to have a further MRI scan of your hip after the surgery. The scan will happen at least 6 weeks after your operation and will help us to analyse the surgery that has been undertaken.

What are the possible risks of taking part?

The treatments are designed to help you, however, this cannot be guaranteed. The individual risks of each treatment are outlined below:

- **Personalised Hip Therapy -** There are some small risks with pain medications and joint injections. A hip joint injection carries a very small risk of infection and bruising. However, the main risk is muscle soreness and short-term increases in pain from the exercises that you will undertake. Generally the risks of this treatment are much lower than hip arthroscopy (surgery)

- **Hip Arthroscopy –** about 1 in 50 people have specific complications from hip arthroscopy. One very rare but serious risk is a break (fracture) of the hip during the surgery. If this happened you would need an additional operation to fix the break. Other risks of hip arthroscopy include:

  - Infection within the joint or around the wounds. This can sometimes be treated with antibiotics alone. In more serious cases it requires a further procedure to washout the hip.
  - Bleeding from the wounds, but this is usually a very small amount and quickly settles.
  - Numbness in groin, leg or foot. To undertake hip arthroscopy we need to apply a pulling force on your leg in order to access the hip joint. This can cause some numbness in your groin, leg or foot as a result. This usually resolves within a few hours or days after the procedure.

For this study, both treatment options may include the use of ionising radiation, but they are not in addition to what would normally be received if they were occurring outside of this study. Although all radiation you receive builds up over your lifetime, the small doses received from either of these treatments should not create a significant risk to your health. The maximum amount of radiation from either treatment is comparable to 40 normal chest X-Ray and equivalent to 3.5 months of exposure to natural background radiation.

How do these treatments work?

Personalised Hip Therapy – this therapy works by allowing soft tissues which are damaged and painful as a result of hip impingement, such as the labrum, a period of relative rest, so that they can heal naturally. This can take up to several weeks or months. During this period you will have learnt and practised many exercises that improve the movement and control of the hip and local joints (such as your lower back and pelvis), which should ensure that your hip impingement can no longer

occur, and that damaged soft tissues, such as the labrum, can continue to heal.Hip Arthroscopy – this procedure relies on surgically removing bits of bone from around the hip so that they no longer rub together and damage the soft tissues such as the labrum. Once the bits of bone have been removed, a period of rehabilitation is required so that the soft tissues can continue to heal.

One of the long-term concerns with hip impingement is that you have an increased risk of developing arthritis of the hip. It is really important that you know that at the moment we have no evidence that any treatment (including personalised hip therapy or hip arthroscopy) will have any effect on whether you subsequently develop arthritis of your hip. However by taking part in this study it will help us in the long term to determine if either of these two treatments can help prevent arthritis.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone from our research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor. If you decide to continue in the study you might be asked to sign an updated consent form. Also, on receiving new information, we might consider it to be in your best interests to withdraw you from the study. If this happens we will explain the reasons to you and arrange for your care to continue.

What happens when the research study stops?

You will be in the study for one year. If you are still having problems after this time, we will arrange for you to see your hip specialist to continue your care.

What if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick (contact Miss Nicola Owen, Deputy Registrar, 02476 522713) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. For independent advice contact the PALS service (Patient Advice Liaison Service) at Freephone 0800 0284203.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and will not be shared with anyone outside of your direct care team. Research data including your name and address will be sent to the University of Warwick so that research staff can stay in touch with you over the course of the year, and send you follow-up questionnaires at 6 and 12 months by post. These details will be sent from the hospital by secure means, and kept in locked filing cabinets or in password-protected computer databases accessible only to essential research

personnel at the University of Warwick. All other information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. If you have hip arthroscopy an anonymised copy of your MRI will be sent electronically via a secure system to Clinical Graphics B.V. based in the Netherlands. If you agree, your GP and other doctors who may treat you, but are not part of this study, will be notified that you are taking part in this study.

What will happen to the results of the research study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please contact the study coordinator Rachel Hobson on 02476-968629 or email: ukfashion@warwick.ac.uk

Who has reviewed this project?

This study has been reviewed and approved by NRES Committee West Midlands - Edgbaston. Approval was granted on 1st May, 2014.

Contacts for further information

If at any time, you would like further information about the study, you may contact the study coordinator, Rachel Hobson, by either telephoning 02476 968629 or emailing ukfashion@warwick.ac.uk

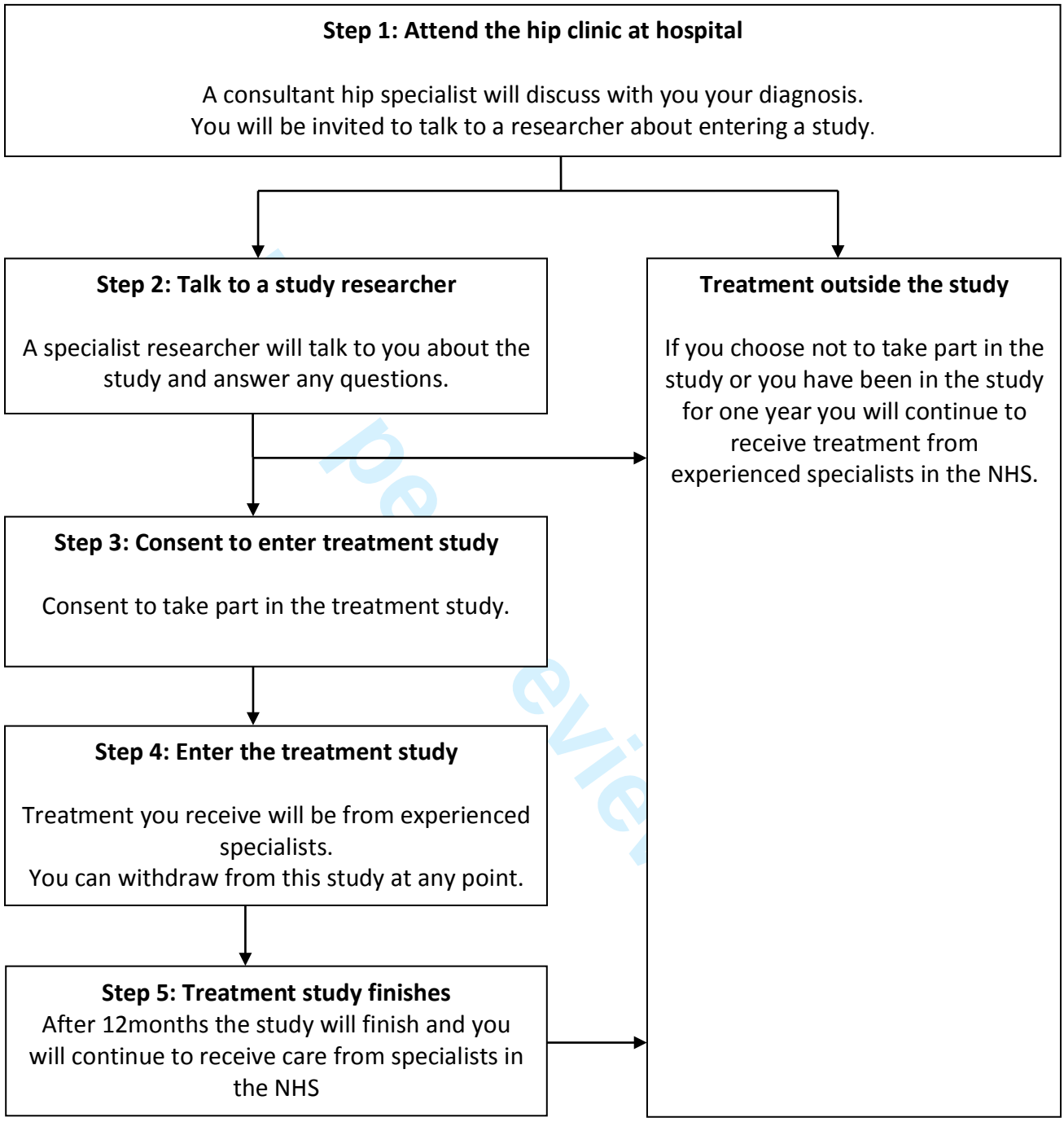
Or you can contact your local research lead, Mr Malviya Telephone 01670 529781 or Christine Dobb 0344 811 8111 extension 4561 or Professor Damian Griffin, who is the overall lead for this study on 02476 968618.

Where can I get additional information?

As well as the researcher and your surgeon who can provide advice and guidance, we have developed a website http://www2.warwick.ac.uk/fac/med/research/csri/orthopaedics/research/fulllist/fashion/

This website provides additional useful information about hip impingement and its treatments, including a series of answers to frequently asked questions. In addition, it provides internet links to other trusted sources of information.

STEP by STEP guide to the study



UK FASHIoN

Recording your Consultations

Chief Investigator Professor Damian Griffin

Patient Information Sheet

You are invited to take part in a research study. Your participation in the research is completely voluntary, but your involvement would help us to care for patients like you in the future. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve – this is explained below.

What is the purpose of the research study?

The aim of this research study is to find out what information is explained to you by specialists in hip problems. The information we obtain, will help us plan future research studies looking at hip problems.

What will happen if I take part?

If you agree to take part, you will be asked to sign a consent form. During your consultations, your conversations will be recorded on a tape recorder. The recorded discussions will be written out and analysed by researchers at the University of Warwick. At any stage during the consultations, you may ask for the recording to be stopped without giving a reason.

What are the possible benefits to you of taking part?

There are no specific benefits for you in taking part. The information we get from this study will help us to plan future research studies in patients with hip problems.

Will my taking part remain confidential?

All information which is collected will be kept strictly confidential, it will not be shared with anyone outside of your direct care team. Copies of the anonymised interviews will be kept in a secure place, for 5 years, and then destroyed.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the standard of care you receive.

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you may contact Mrs Nicola Owen, deputy registrar at the University of Warwick on 02476 522785.

Who has reviewed this survey?

This study has been reviewed and approved by NRES Committee West Midlands -Edgbaston. Approval for this study was gained on 1st May, 2014.

Contacts for further information;

If you have any questions, please do not hesitate to ask your consultant at the start of your consultations. Or, for further information about this research project you may contact the study coordinator, Mrs Rachel Hobson by either telephoning 02476 968629 or emailing fashion@warwick.ac.uk, or Professor Damian Griffin, who is the overall lead of this study on 0247 6869618.

For independent advice contact the PALS service (Patient Advice Liaison Service) at freephone 0800 0284203.

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UK FASHIoN

Chief Investigator: Professor Damian Griffin

CONSENT FORM – UK FASHIoN Study

Site ID ☐☐ Participant ID: ☐☐☐

Please **Initial** Box

1. I confirm that I have read and understand the information sheet dated 20th June, 2014– version 3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Warwick, from regulatory authorities, or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that appropriate personal identifying information will be collected, stored and used by the study office to enable follow-up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality. ☐
5. I understand that information held and managed by The Health and Social Care Information Centre and other central UK NHS bodies may be used in order to help contact me or provide information about my health status. ☐
6. I agree that encrypted anonymised copies of post-operative scans can be sent via electronic transfer to Clinical Graphics B.V. based in the Netherlands. ☐
7. I agree to my GP being informed of my participation. ☐
8. I agree to take part in the above study ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Please ensure the following: -
Original consent form retained in the site file**, 1 copy** for Patient, **1 copy** for Hospital Notes

<< To be printed on local headed paper>>

UK FASHIoN

Chief Investigator: Professor Damian Griffin

CONSENT FORM – Recording Your Consultation

Site ID ☐☐ Screening No.: ☐☐☐☐

Please **Initial** Box

1. I confirm that I have read and understand the information sheet dated 20th June, 2014 – version 3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I give permission that anonymous quotes from my interview may be used in the reporting of this study. ☐

4. I give permission for the interview to be digitally-recorded. ☐

5. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

Please ensure the following:
Original consent form retained in the site file, 1 copy for Patient, 1 copy for Hospital Notes.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	4
Protocol version	3	Date and version identifier	6
Funding	4	Sources and types of financial, material, and other support	20-21
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	21
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11-12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15 (+ figure1)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8, 13-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11-12

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8-9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19-20
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	See full trial protocol.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
	31b	Authorship eligibility guidelines and any intended use of professional writers	1
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.