UK FASHIoN: feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care

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Scientific summary

Arthroscopic surgery for hip impingement

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Scientific summary

Background

The human hip is a ball and socket joint in which the femoral head (the ball) articulates with the cup-shaped acetabulum (the socket). However, the femoral head is not always spherical and the acetabulum is sometimes too deep. During movement, hips with these features impinge, a condition called femoroacetabular impingement (FAI). FAI can damage the cartilage that lines the hip joint. FAI typically causes groin pain, which many patients describe as severe and distressing, and which interferes with sport, work and everyday activities. Recent research shows a likely association between hip impingement and the subsequent development of osteoarthritis of the hip.

A conservative approach to treating FAI includes using analgesia, modifying activities to try to prevent impingement and regimes of exercise and physiotherapy. There are a few observational case series reporting that this conventional treatment method can alleviate the symptoms of FAI.

Recently, there has been a rapid growth in the technology and enthusiasm for surgical treatment of FAI. Open surgery has been used, but arthroscopic (keyhole) surgery has rapidly grown in popularity. During hip arthroscopy, under general anaesthesia, the surgeon passes a small telescope into the hip joint and uses long, thin, powered burrs to reshape the hip joint. Case series (without controls) have been reported which suggest that patients experience an improvement in pain and function. Some surgeons now suggest that arthroscopy is superior to conventional non-operative treatment strategies.

We performed a feasibility study to establish whether or not a randomised controlled trial (RCT) of hip arthroscopy compared with best conventional care in patients with FAI was possible and to inform the design of such a study. Our main concern was whether or not patients could be recruited and we focused on this in the design of the feasibility study, including a pilot RCT.

Aim and objectives

The aim of this study was to assess the feasibility of a RCT of hip arthroscopy compared with best conventional care in patients with FAI.

The objectives of this study are listed below:

- to estimate the annual number of patients offered hip arthroscopy for FAI in the UK
- to explore clinicians' and patients' attitudes to recruitment into a RCT of FAI treatments
- to develop a consensus for eligibility criteria, an operative care protocol and a best conservative care protocol among clinicians who manage patients with FAI
- to consider possible outcome measures and estimate the sample size for a full RCT
- to develop trial procedures and patient information material to maximise recruitment rate
- to estimate recruitment rate to a full RCT
- to test trial procedures and to ensure acceptability of the trial to ethics and research and development (R&D) committees
- to test measures of treatment fidelity, for both arthroscopy and best conservative care
- to understand the recruitment process so that any difficulties related to design or conduct can be addressed in a full trial.

Methods

The feasibility study was divided into three parts: pre-pilot work, a pilot study and a qualitative recruitment intervention (QRI).

Pre-pilot work

Workload

A list of orthopaedic clinical directors of NHS health care boards and trusts was established. These directors were then contacted to identify all FAI surgeons working within their departments. We asked each FAI surgeon for details of their own FAI surgical workload data for the financial year 2011/12.

Clinicians' attitudes to randomisation

Semistructured interviews were carried out with a sample of orthopaedic surgeons, sports physicians and physiotherapists. The interviews were analysed and relevant elements of clinical decision-making in relation to RCT participation were identified.

Developing eligibility criteria for a randomised controlled trial and designing an operative protocol

Draft eligibility criteria and an operative protocol were prepared. Internationally recognised expert surgeons in this field were invited to comment on these provisional documents. The feedback they provided was used to modify the two documents, which were then recirculated for further comment.

Design of a best conservative care treatment protocol for femoroacetabular impingement

An international and UK sample of physiotherapists who treat FAI was recruited by identifying and advertising to relevant networks of physiotherapists. We used evidence from a systematic review of non-operative care for FAI and a number of consensus-gathering methods to develop a protocol of best conventional care.

Patients' attitudes towards randomisation and design of patient information material for a randomised controlled trial

We purposively sampled patients who had been treated for FAI and used semistructured interviews to explore their attitudes towards participation in a RCT. We also worked with them to develop patient information for the RCT, seeking to ensure optimum recruitment.

Consideration of outcome measures and sample size for a full randomised controlled trial

We reviewed the available literature on outcome measures for FAI treatment and explored which to use in our interviews with surgeons. We used information on minimum clinically important difference, estimated effect size and standard deviation to estimate sample size.

Pilot study

A multicentre pilot RCT was performed in 10 NHS hospitals.

Patients were included if they met the inclusion criteria: aged $\geq$ 16 years; symptoms of hip pain; radiographic evidence of FAI on plain radiographs and cross-sectional imaging; treating surgeon believes that they would benefit from arthroscopic FAI surgery; and able to give written informed consent and able to participate fully in the interventions. Patients were excluded if they had 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 FAI surgery (shape-changing surgery) on the side being considered for treatment; or existing osteoarthritis, defined as Tönnis grade of > 1, or more than 2-mm loss of superior joint space width on anteroposterior pelvic radiograph.

Eligible patients were identified by research associates and surgeons taking part in the trial. The consultations between the patient and surgeon were recorded (the diagnostic consultation). Eligible patients who were then approached to take part in the trial also had the recruitment consultation recorded, a process that was typically undertaken by a trained research associate. Patients were randomised 1 : 1 to receive either hip arthroscopy or best conservative care.

Patients were followed up at 3, 6 and 12 months after randomisation using patient-reported outcome measures for hip pain and function [Non-Arthritic Hip Score and International Hip Outcome Tool (iHOT-33)] and quality of life (Short Form questionnaire-12 items and European Quality of Life-5 Dimensions). Patients were also asked to report any medical complications they experienced during the trial and to record any expenses experienced as a result of their treatment.

Qualitative recruitment intervention

A QRI observed recruitment as it happened through analysis of recordings of diagnostic and treatment consultations. It was used to understand potential or actual obstacles to recruitment and to inform a plan to address them. The nature of the IQR meant that the research moulded itself around the needs of the trial as it progressed and was completed when theoretical saturation was reached (i.e. new data collection did not materially add to the findings).

Results

Pre-pilot work

Workload

There are at least 120 substantive NHS consultant surgeons treating FAI. Collectively these surgeons performed 2399 operations for FAI in 2011/12; 1908 were performed by hip arthroscopy, compared with 491 by open surgery. Thirty-four hospital trusts had a workload of 20 or more hip arthroscopies for FAI in a year.

Clinicians' attitudes to randomisation

We interviewed 18 of the highest-volume surgeons to explore their views about a trial comparing hip arthroscopy and best conventional care in patients with FAI. One surgeon declined to participate in the trial owing to lack of equipoise, five had a bias towards surgery but recognised the need for a trial and were prepared to randomise patients, and 12 expressed equipoise and were keen to take part in a trial.

Developing eligibility criteria for a randomised controlled trial and designing an operative protocol

The eligibility criteria and operative protocol were initially designed by the investigators and then refined in collaboration with an international group of 16 expert surgeons specialising in arthroscopic FAI surgery. The criteria and protocol were modified after discussion with a further sample of 14 UK specialist hip surgeons who had experience of treating patients with FAI and were likely collaborators for a full RCT.

Design of a best conservative care treatment protocol for femoroacetabular impingement

Our survey of physiotherapists showed that there is no currently accepted 'best' physiotherapy practice for patients with FAI, in the UK or internationally, and current practice varies widely. We developed a new protocol for the physiotherapy-led intervention. Many patients had previous conservative care (including some form of physiotherapy treatments) prior to considering surgery and attending a consultation with a surgeon, so we developed a conservative care protocol that was sufficiently different (in terms of number of treatment sessions, length of treatment period overall and the content of the treatment) for patients to consider it a new treatment. Recruiting patients from surgical settings to a randomised trial comparing surgery with a non-surgical intervention is known to be challenging and so it

was important that the conservative care intervention in this trial was considered by both participating clinicians and patients to be a credible alternative to surgery. We developed a protocol with four core components: (1) a detailed patient assessment; (2) education and advice about FAI; (3) help with pain relief (which may include up to two radiography- or ultrasonography-guided intra-articular steroid injections if pain prevents performance of the exercise programme); and (4) an exercise programme that has the key features of individualisation, supervision and progression. It is delivered over a minimum of 12 weeks and includes a minimum of six physiotherapy-led, one-to-one treatment sessions. We used a patient focus group to choose the most acceptable name for this protocol of best conventional care. The group made it clear that we should express that this was a coherent and valid alternative to surgery and different from physiotherapy likely to have been received already, and recommended the name personalised hip therapy (PHT). In the development of PHT we struck a balance between the need for a meaningful comparator for hip arthroscopy, the need to ensure PHT is different from previous physiotherapy that FAI patients may have experienced and the need for PHT to be deliverable in the NHS outside a trial. UK physiotherapists and patients felt that PHT was 'best' in that not all patients currently receive such a comprehensive package, but 'conventional' in that all its elements are widely used and the package is deliverable within usual constraints in the NHS.

Patients' attitudes towards randomisation and design of patient information material for a randomised controlled trial

Our sample included 18 patients who had been treated for FAI. Fourteen had received arthroscopic surgery, four had received physiotherapy and steroid injections and one had both. Symptoms of FAI had affected their work, recreation and day-to-day activities and many reported a great sense of relief when a diagnosis was made. Patients said that both surgical and conventional care would be acceptable. Patients were enthusiastic about research in this field and about being involved, but had reservations about some of the language involved. To them, 'trial', 'random' and '50 : 50 chance' implied a lack of personalised care. All of these patients said that they would have been prepared to take part in a RCT as long as the treatment options and uncertainty around them had been fully explained, the treatment they received had been personalised for them and they were assured that their care would be continued whatever happened in the research.

Consideration of outcome measures and sample size for a full randomised controlled trial

The iHOT-33 was the preferred outcome measure because there was extensive patient involvement in item generation, a minimum clinically important difference (MCID) has been independently determined and this instrument has been chosen as the principal outcome measure for the UK Non-Arthritic Hip Registry mandated by the National Institute for Health and Care Excellence. We estimated that 292 participants would be required for analysis to detect an effect difference equal to the MCID (standardised effect difference of 0.38) with a power of 90%. Assuming a follow-up rate of 85%, this implies a sample size of 344 participants.

Pilot study

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

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

Two patients declined their allocated intervention (1/21 surgery and 1/21 PHT) while one patient (1/21) allocated to PHT decided to have an operation following randomisation, but prior to starting their allocated treatment. Follow-up rates at the time of writing were 39 out of 42 (93%), 38 out of 42 (90%) and 31 out of 32 (97%) at 3, 6 and 12 months; follow-up will continue to 12 months for all patients.

Measures of fidelity of both hip arthroscopy and best conservative care were practicable and gave confidence to clinicians and researchers in the fidelity of the interventions.

Qualitative recruitment intervention

We recorded and analysed 87 diagnostic and recruitment consultations with 60 new patients during the pilot trial. We identified structural features associated with successful recruitment, such as running targeted clinics, having a dedicated research associate in attendance and ensuring referred patients arrived with expectations of receiving treatment for FAI rather than being told they had been referred for surgery. Common difficulties with recruitment that were identified included poorly balanced presentations of treatment options (when surgery was presented at greater length and more favourably than PHT); graphic descriptions of surgery that may have put patients off that option or discouraged participation; presenting trial information in an order that was confusing for patients; and surgeons going beyond their protocol brief, to explain the trial rather than referring patients to the trial recruiter for this information. We identified where improvements could be made in presenting trial information and in engaging patients to consider participation. We targeted sites where recruitment rates were lower and provided individual confidential feedback for recruiters on good practice and areas for improvement, and with anonymised findings being fed back to all sites.

Conclusion

In a comprehensive feasibility study and multicentre pilot trial, we demonstrated that a RCT of hip arthroscopy compared with best conventional care in patients with FAI is feasible and would be welcomed by patients and clinicians.

Most critically, we showed that recruitment can be successful, with a recruitment rate of 70% of eligible patients on average across nine hospital sites. We have developed the procedures for such a trial and shown that they are practicable.

This feasibility study and pilot trial have enabled us to design a full RCT in 25 sites in the UK with a recruitment period of 20 months and a total sample of 344 participants. Such a trial will answer the pragmatic question of whether or not arthroscopic surgery provides benefit in patients with hip impingement, compared with best conservative care.

We propose that such a trial be initiated.

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